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(54) **APPARATUS AND METHOD FOR STABILIZING ADJACENT BONE PORTIONS**

(52) **U.S. Cl. 623/17.16**

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(57) **ABSTRACT**

(21) **Appl. No.: 13/347,526**

A method and apparatus for stabilizing first and second adjacent bone portions. The method includes the steps of: providing a spacer; providing a stabilizer, with the spacer and stabilizer configured to be movable guidingly, one relative to the other, between a pre-assembly relationship and an operative relationship; and placing the spacer and stabilizer into an operative relationship with the first and second adjacent bone portions. As an incident of the spacer and stabilizer being changed from their pre-assembly relationship into the operative relationship with each other and the first and second bone portions, the spacer, stabilizer and first bone portion cooperate to cause the first bone portion and spacer to be urged towards each other. The method may be carried out by moving the stabilizer and spacer, and all auxiliary parts and handling and assembling instruments, substantially in a single plane along one line or parallel lines.

(22) **Filed: Jan. 10, 2012**

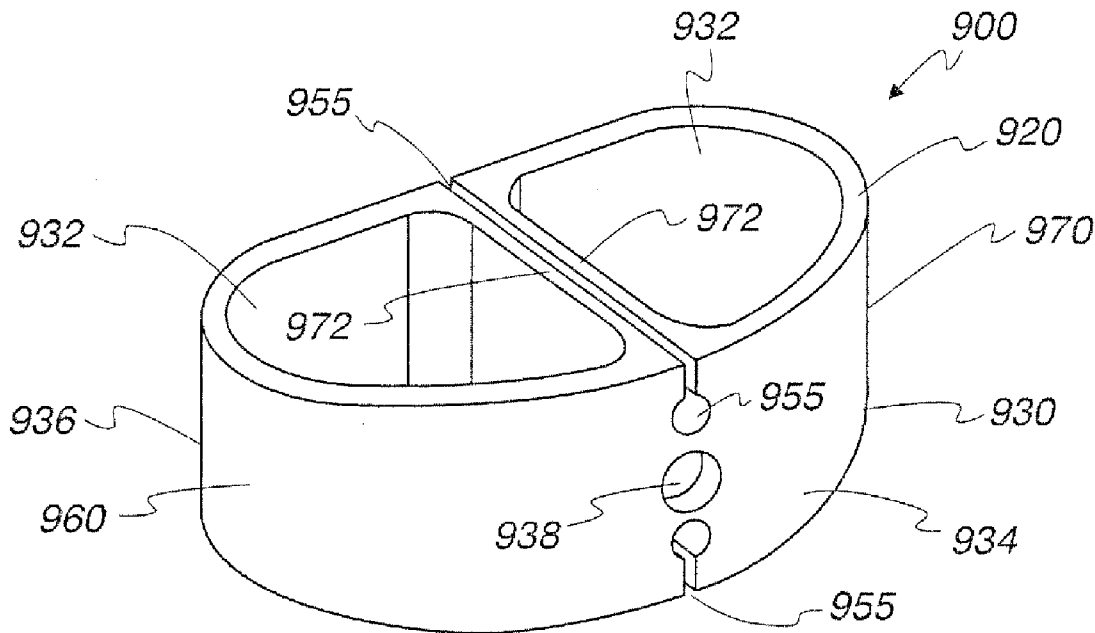
Related U.S. Application Data

(63) Continuation-in-part of application No. 12/692,503, filed on Jan. 22, 2010, now Pat. No. 8,157,865.

(60) Provisional application No. 61/431,235, filed on Jan. 10, 2011.

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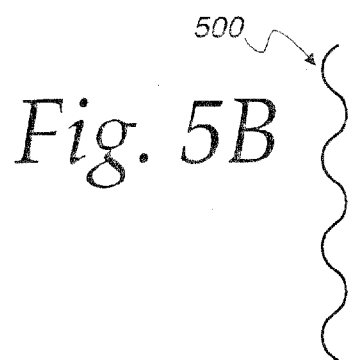
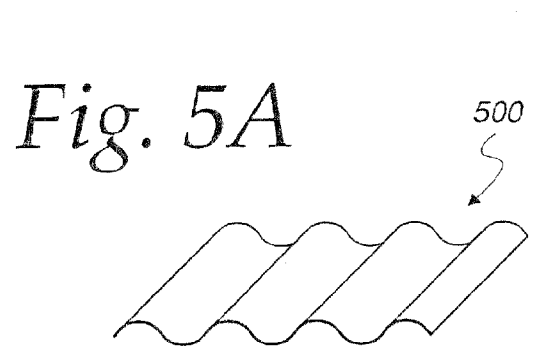
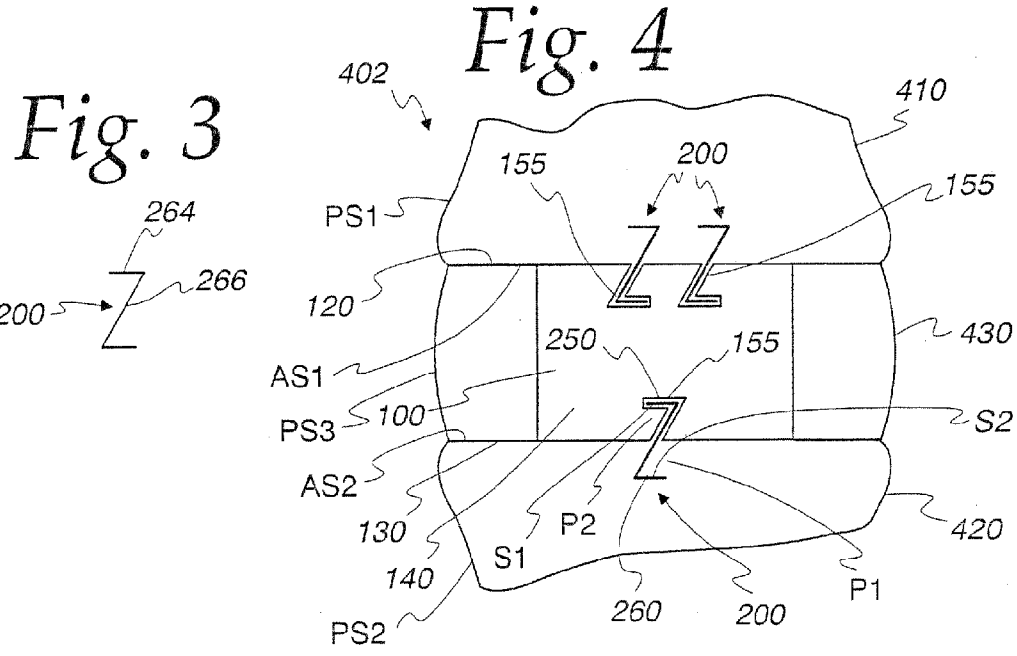
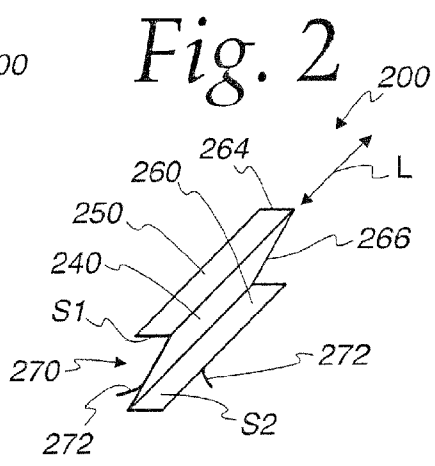
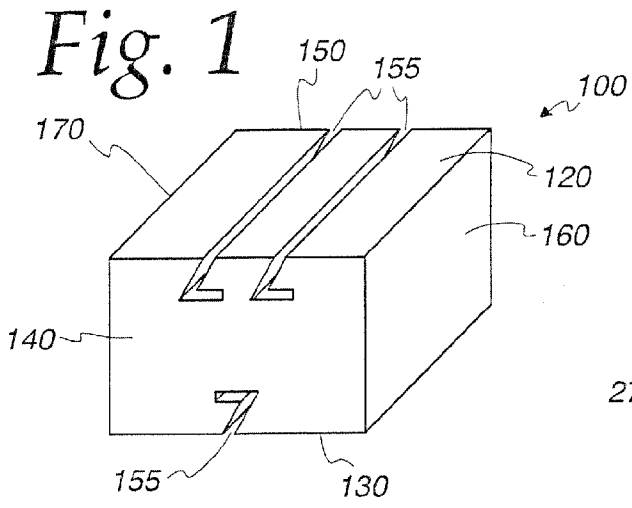


Fig. 6A

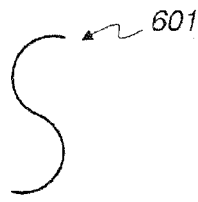


Fig. 6B

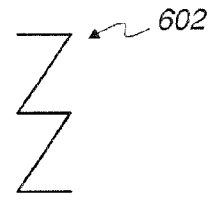


Fig. 6C

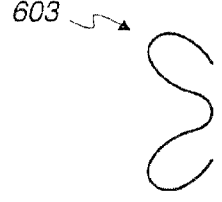


Fig. 6D

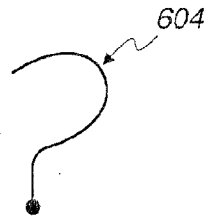


Fig. 6E

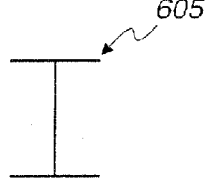


Fig. 6F

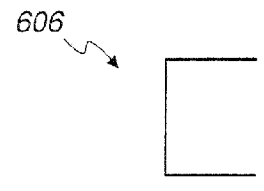


Fig. 6G

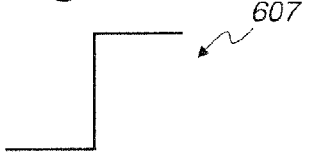


Fig. 6H

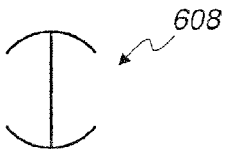


Fig. 6I

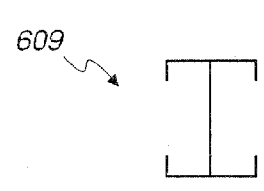


Fig. 6J



Fig. 7

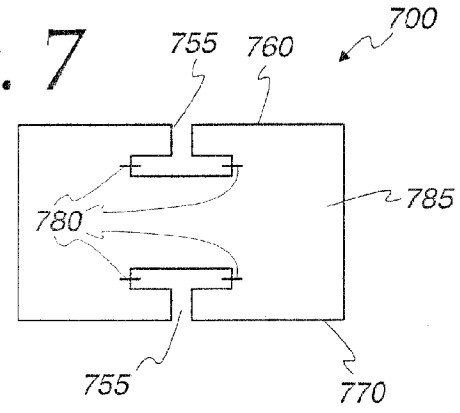


Fig. 8A
(Prior Art)

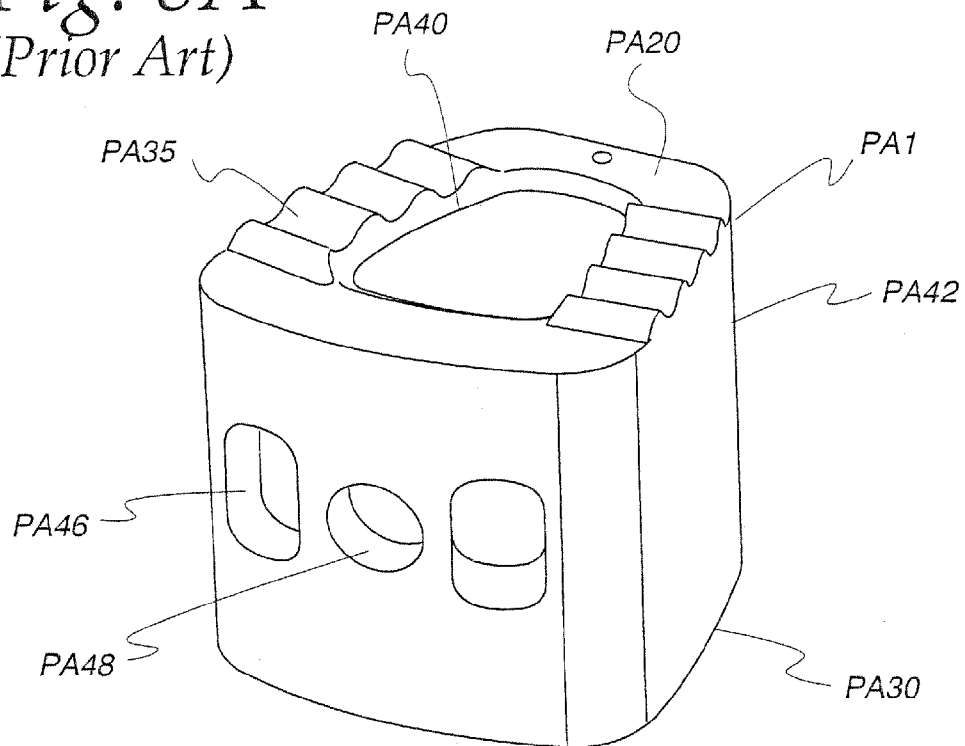


Fig. 8B
(Prior Art)

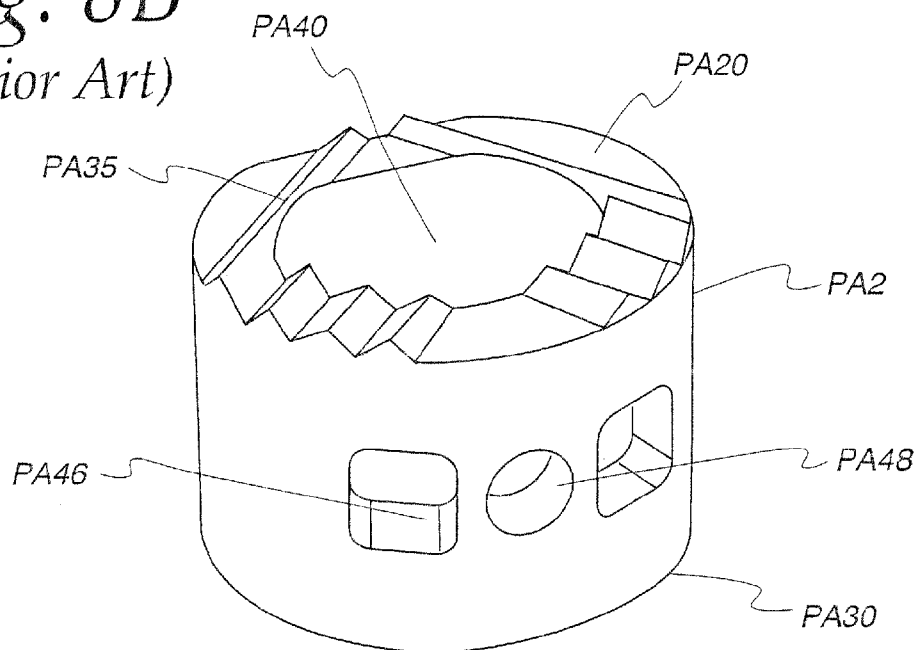


Fig. 8C
(Prior Art)

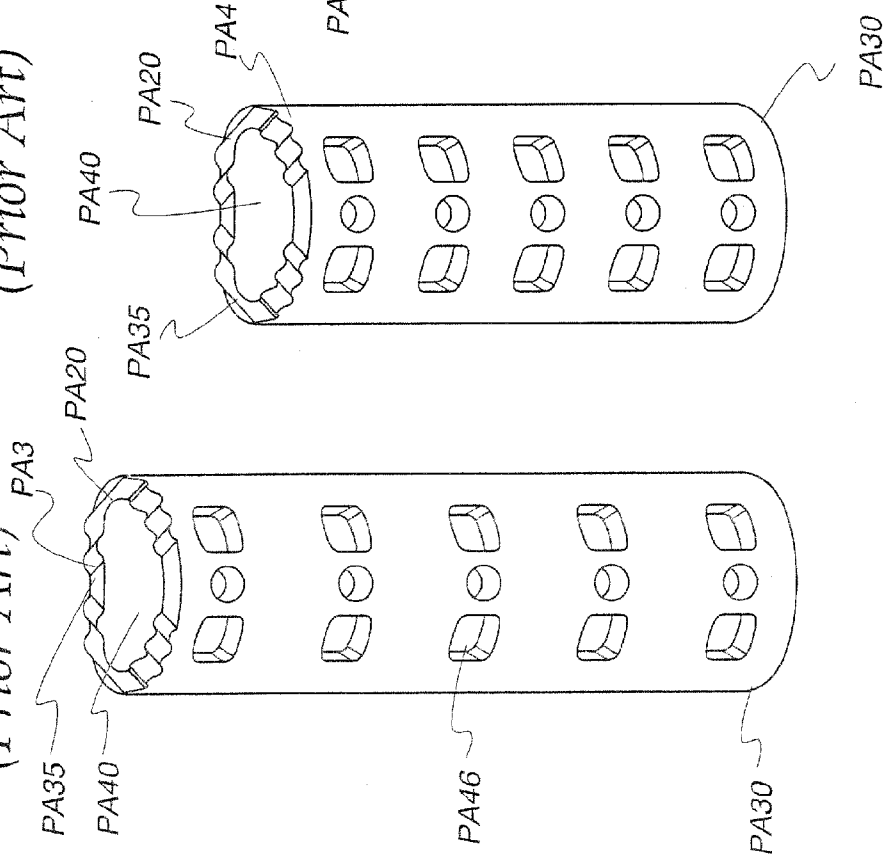


Fig. 8D
(Prior Art)

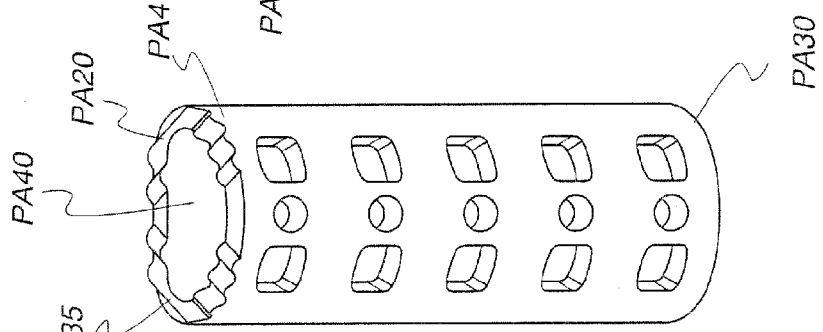


Fig. 8E
(Prior Art)

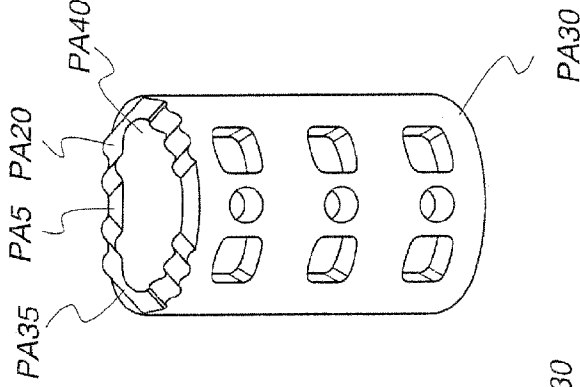


Fig. 8F
(Prior Art)

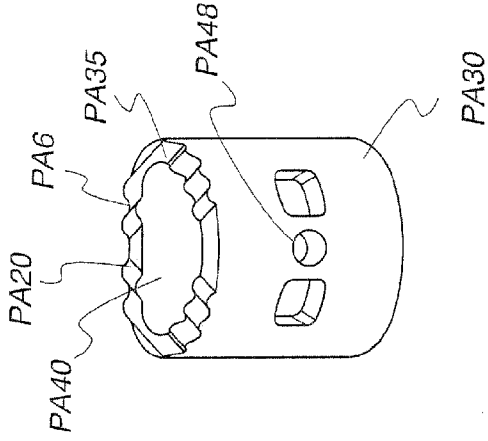


Fig. 8G

(Prior Art)

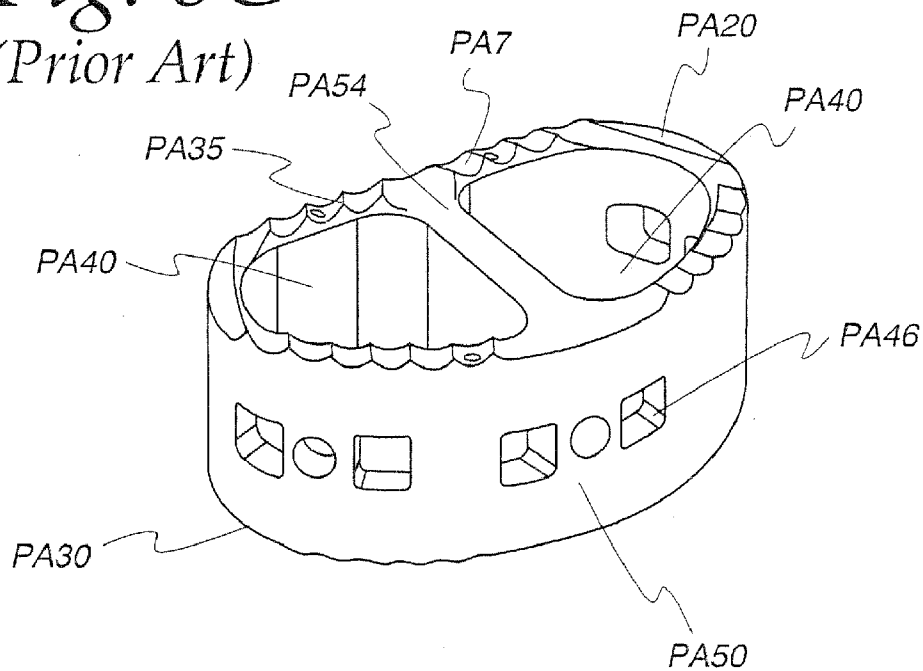


Fig. 8H

(Prior Art)

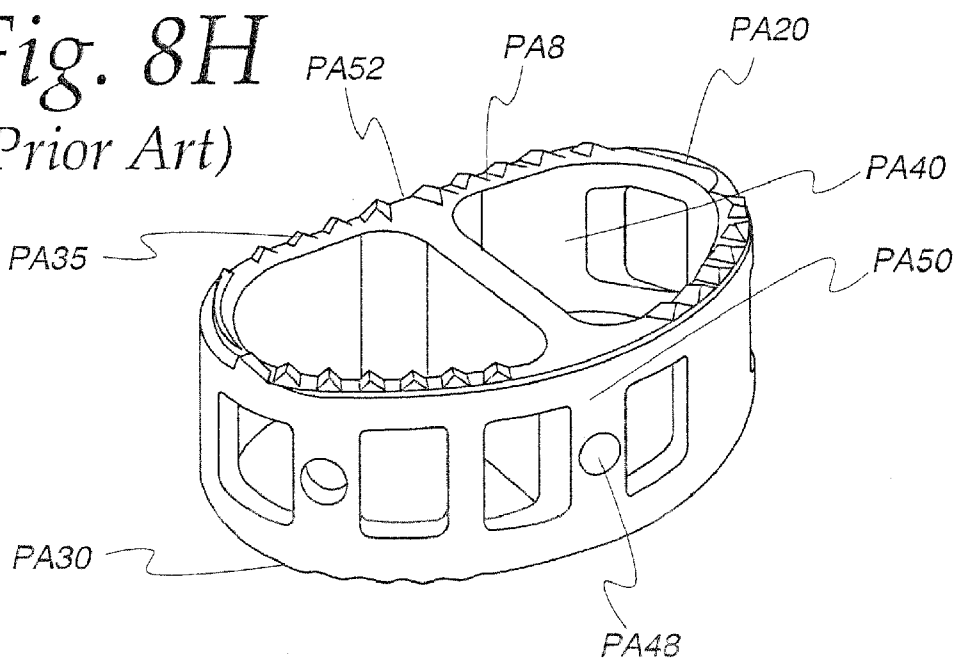


Fig. 8I
(Prior Art)

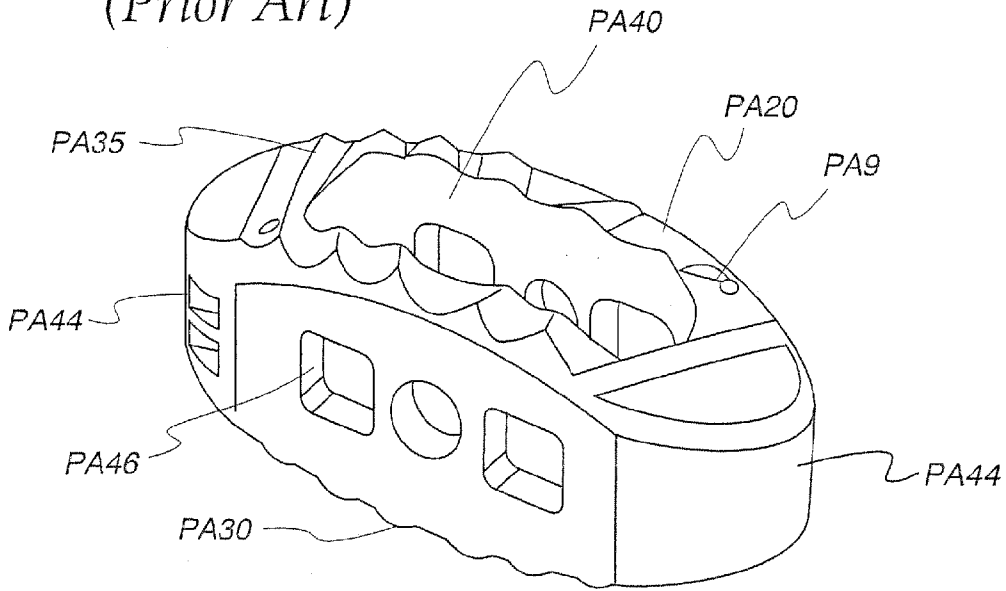


Fig. 8J
(Prior Art)

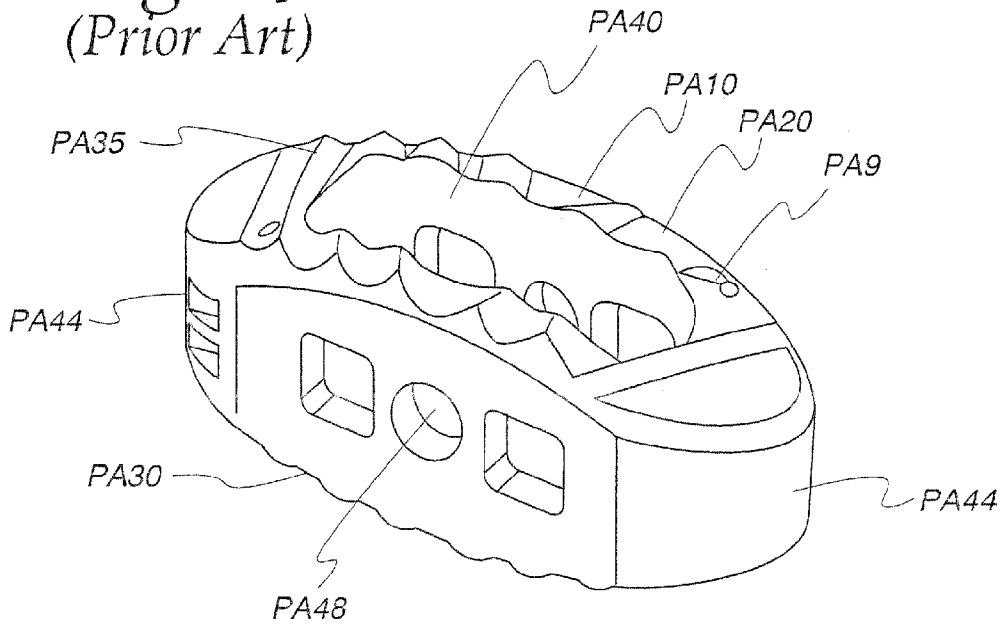


Fig. 8K
(Prior Art)

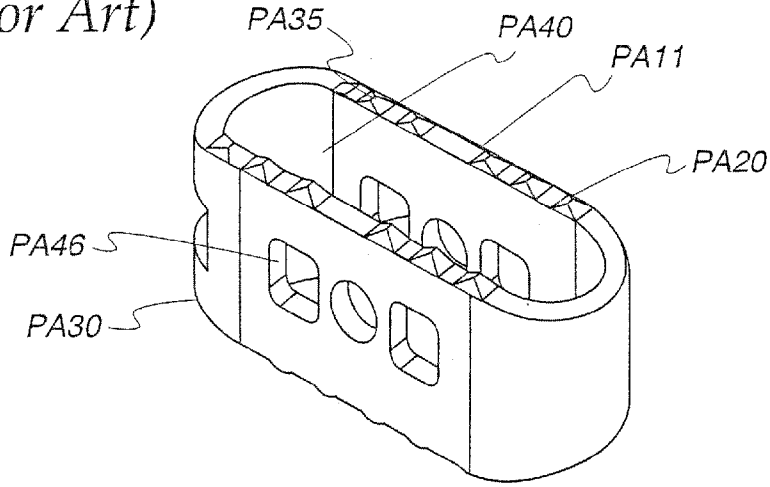


Fig. 8L
(Prior Art)

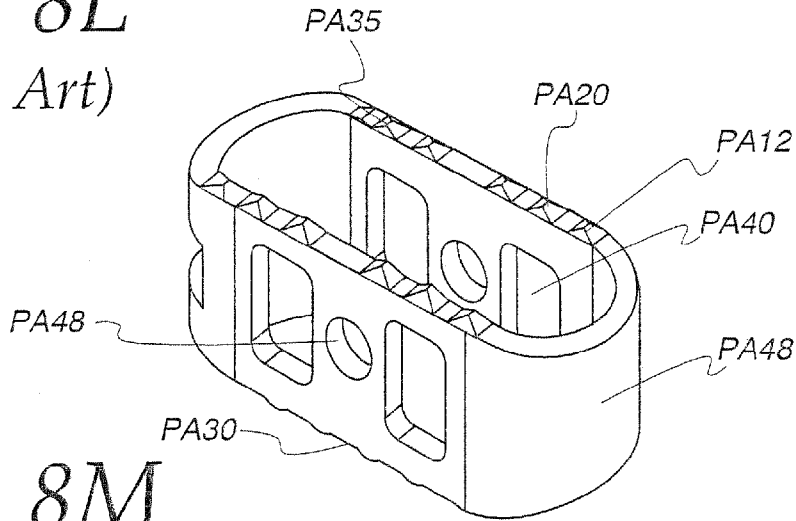


Fig. 8M
(Prior Art)

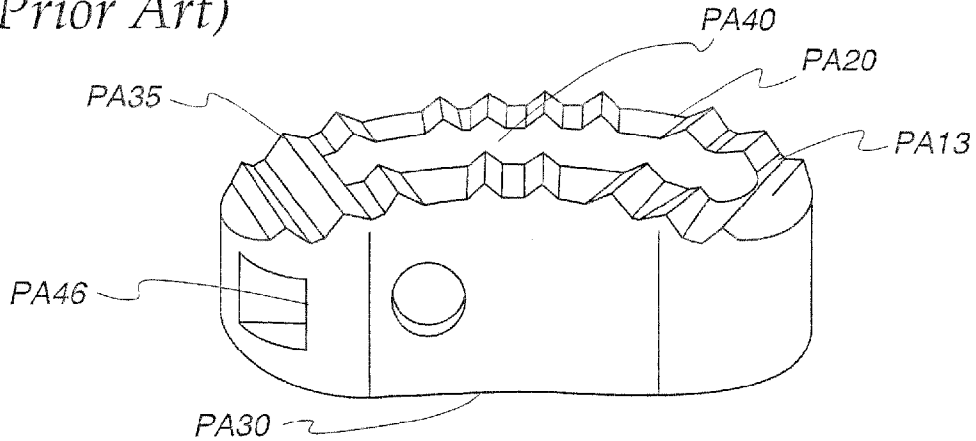


Fig. 9

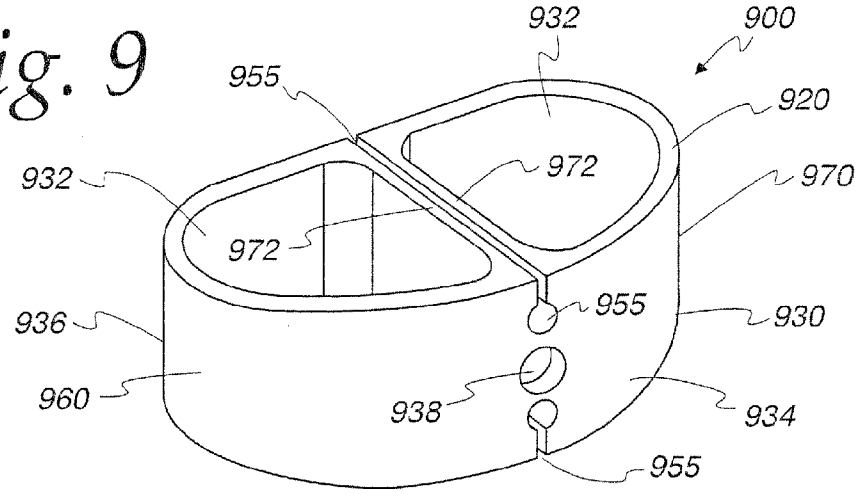


Fig. 10

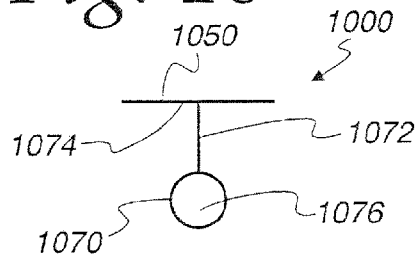


Fig. 11

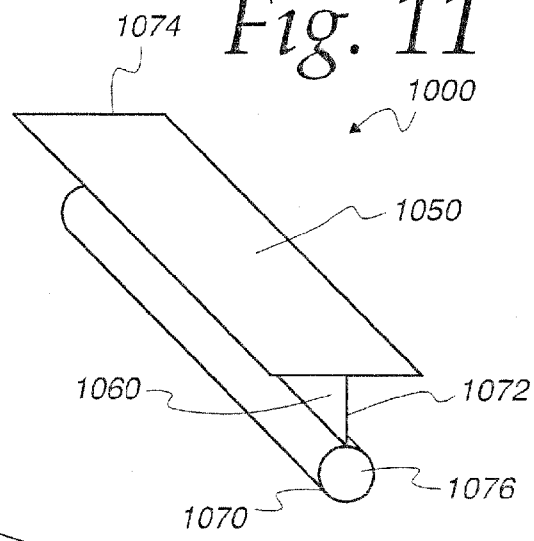


Fig. 12

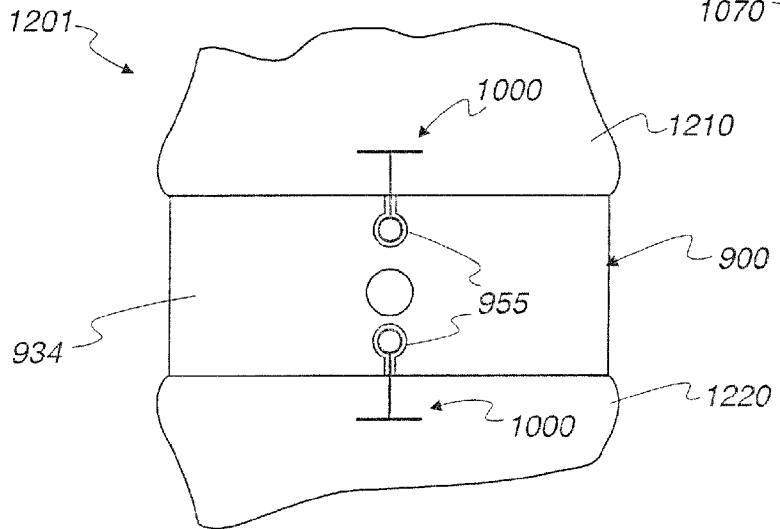


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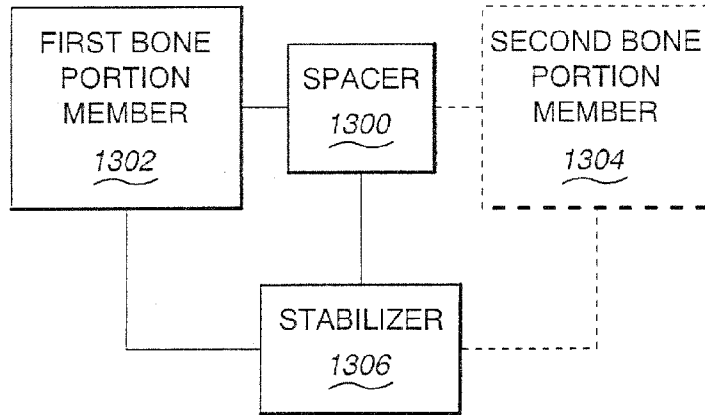


Fig. 14

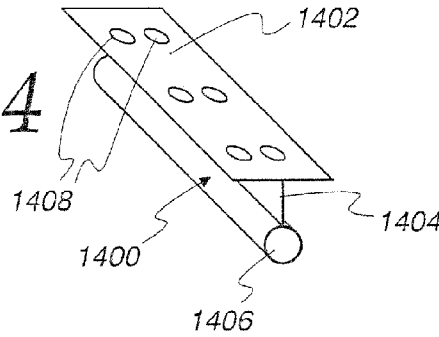
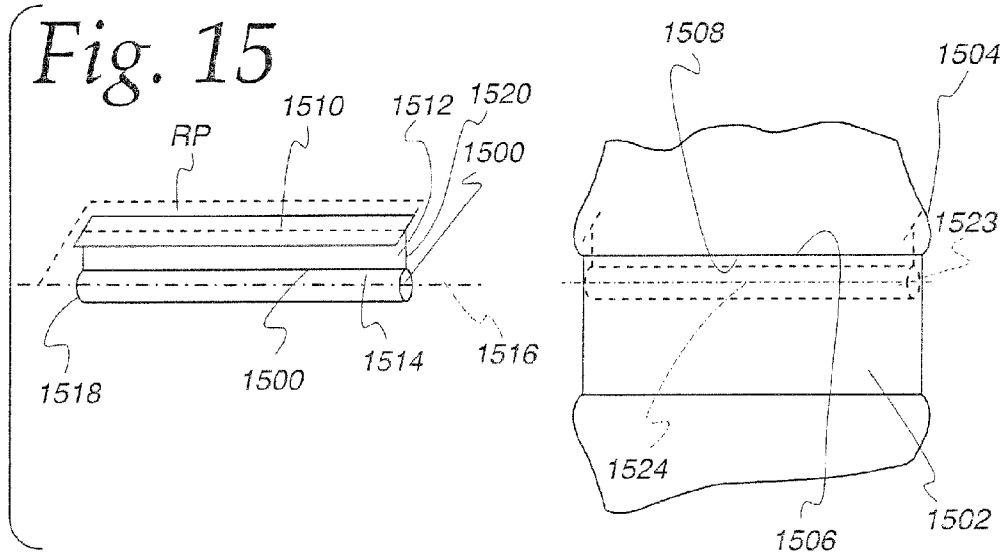


Fig. 15



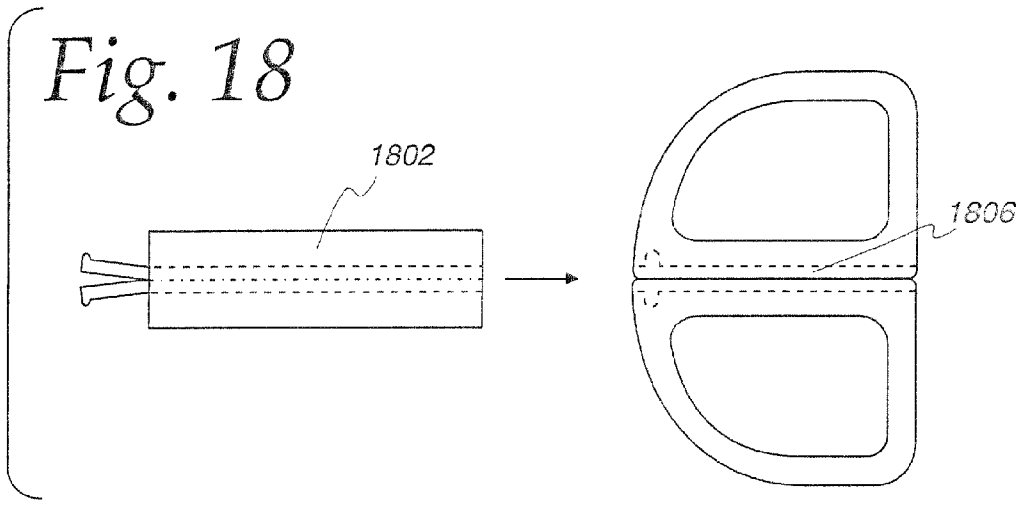
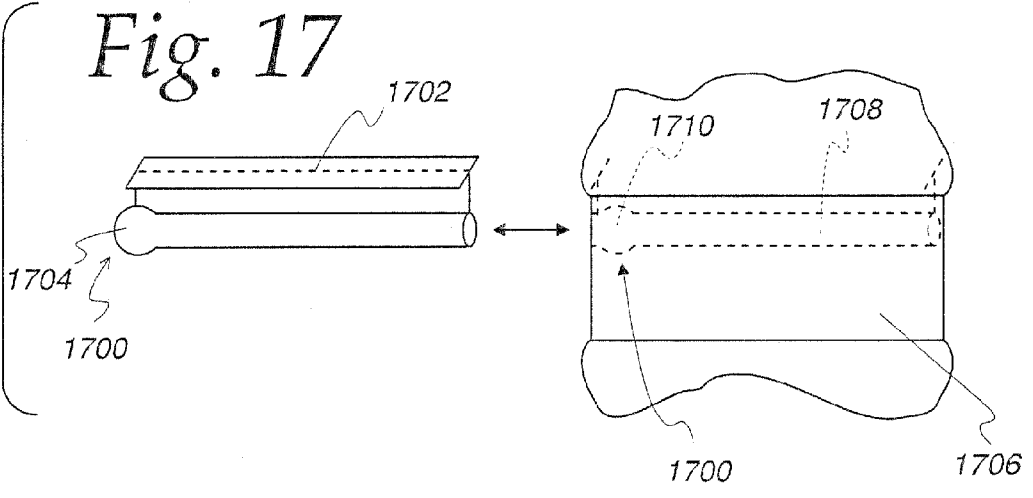
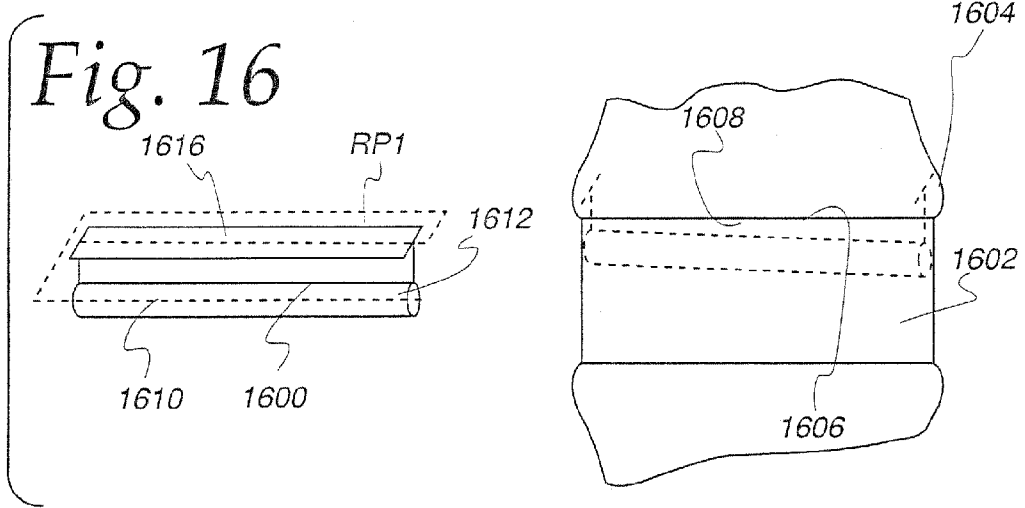


Fig. 19

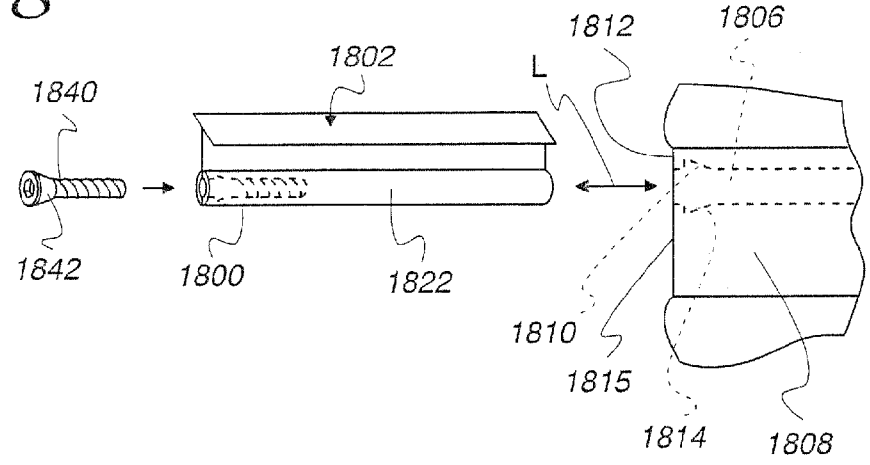


Fig. 20

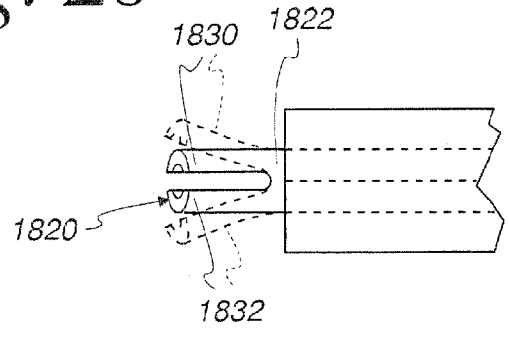
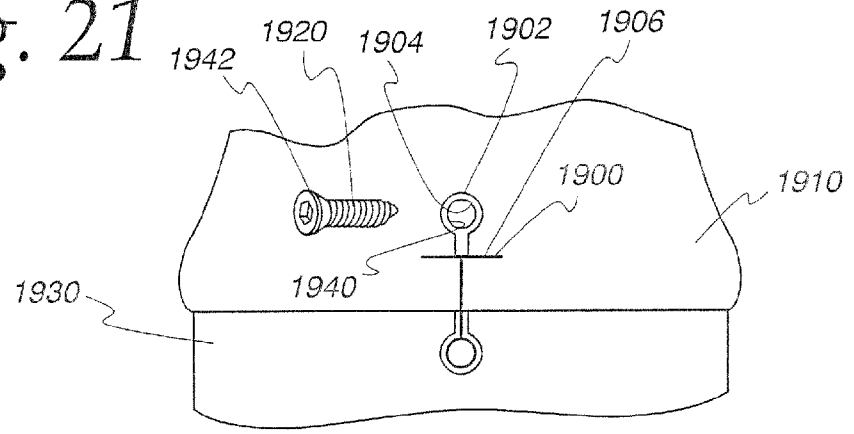


Fig. 21



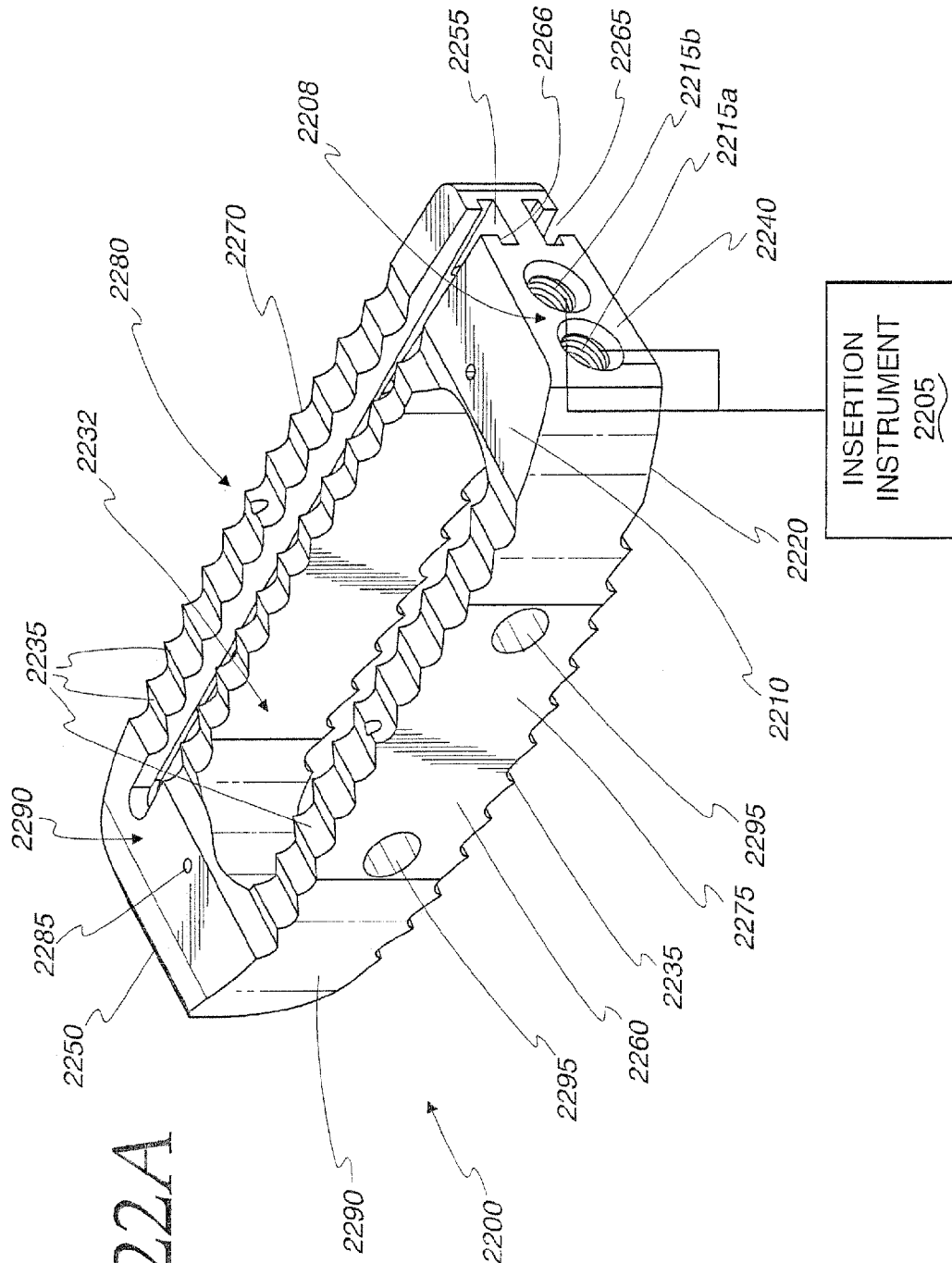


Fig. 22A

Fig. 22B

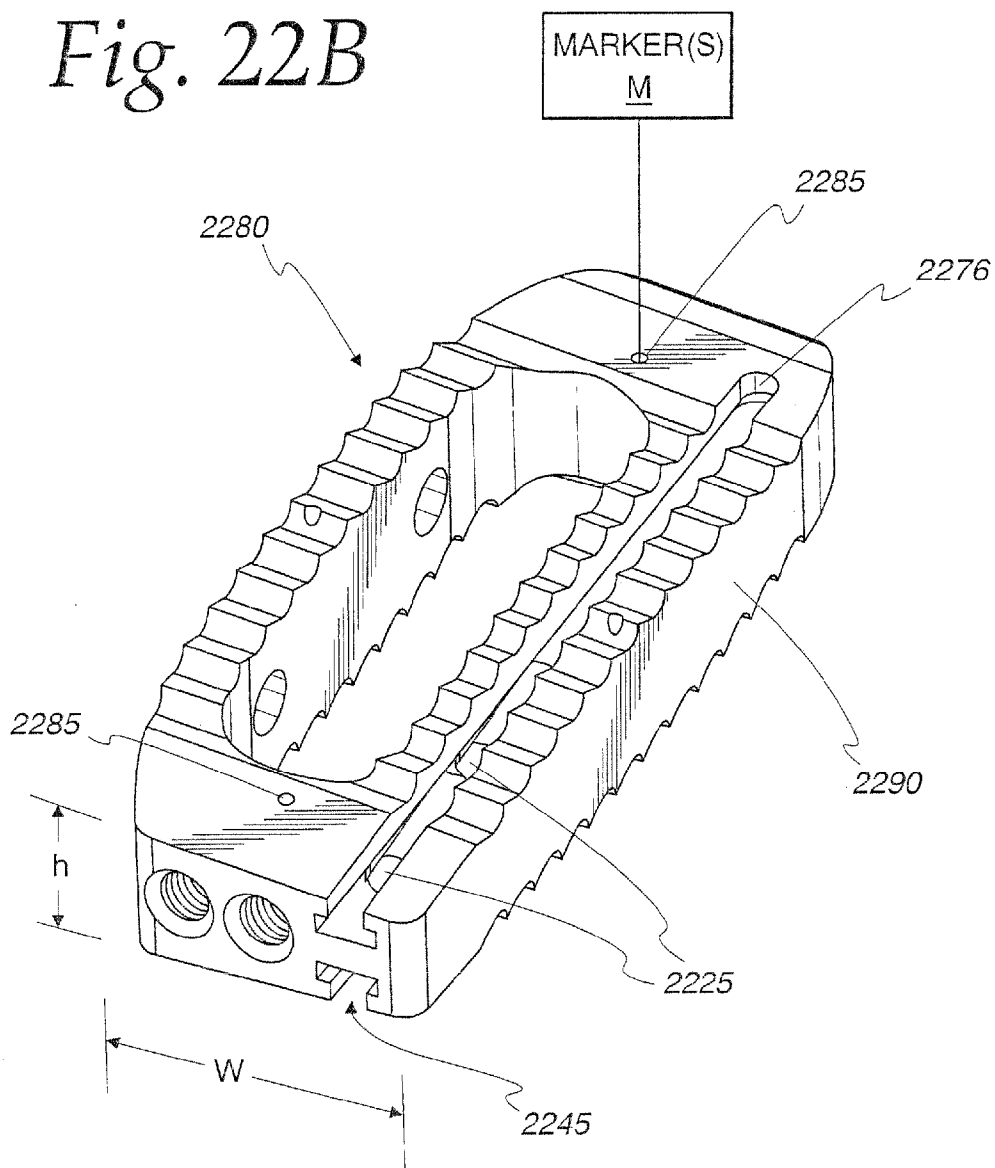


Fig. 22C

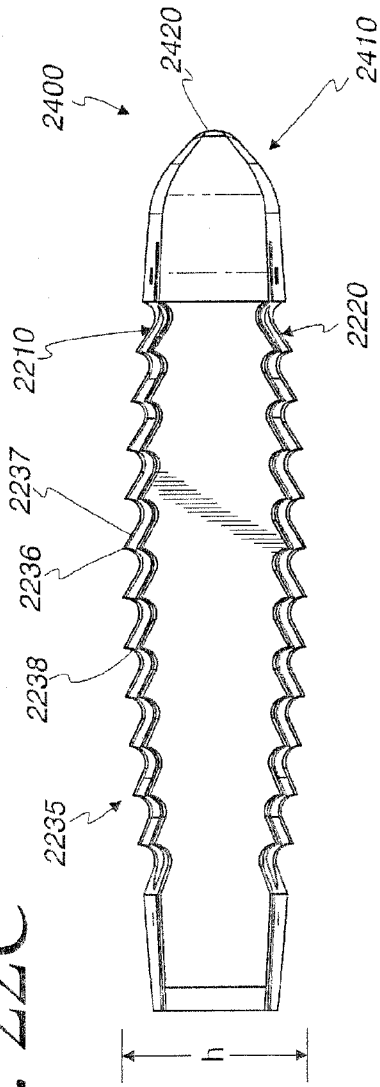


Fig. 22D

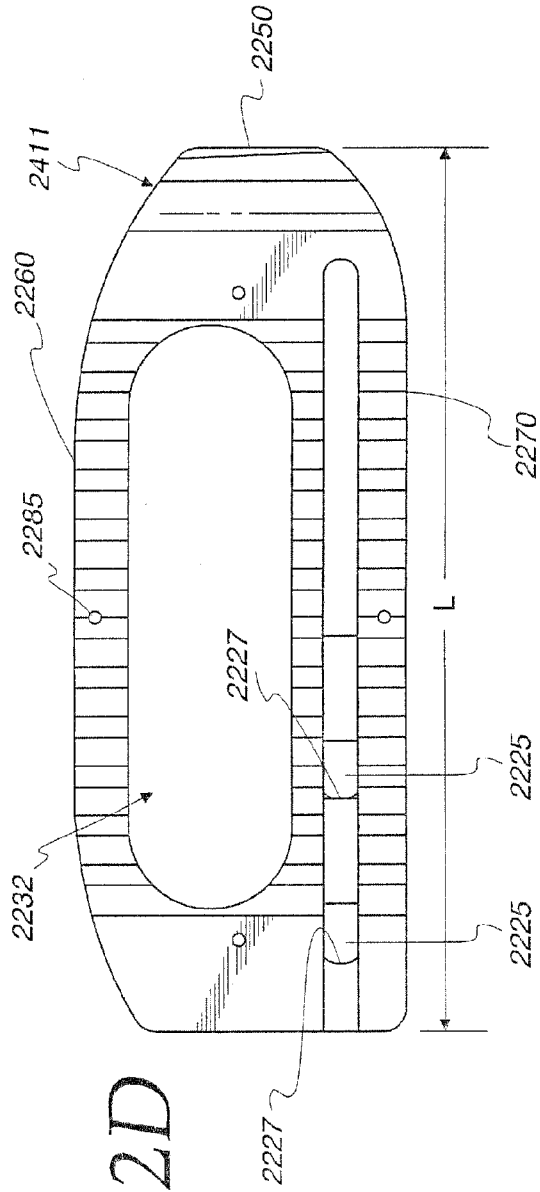


Fig. 23A

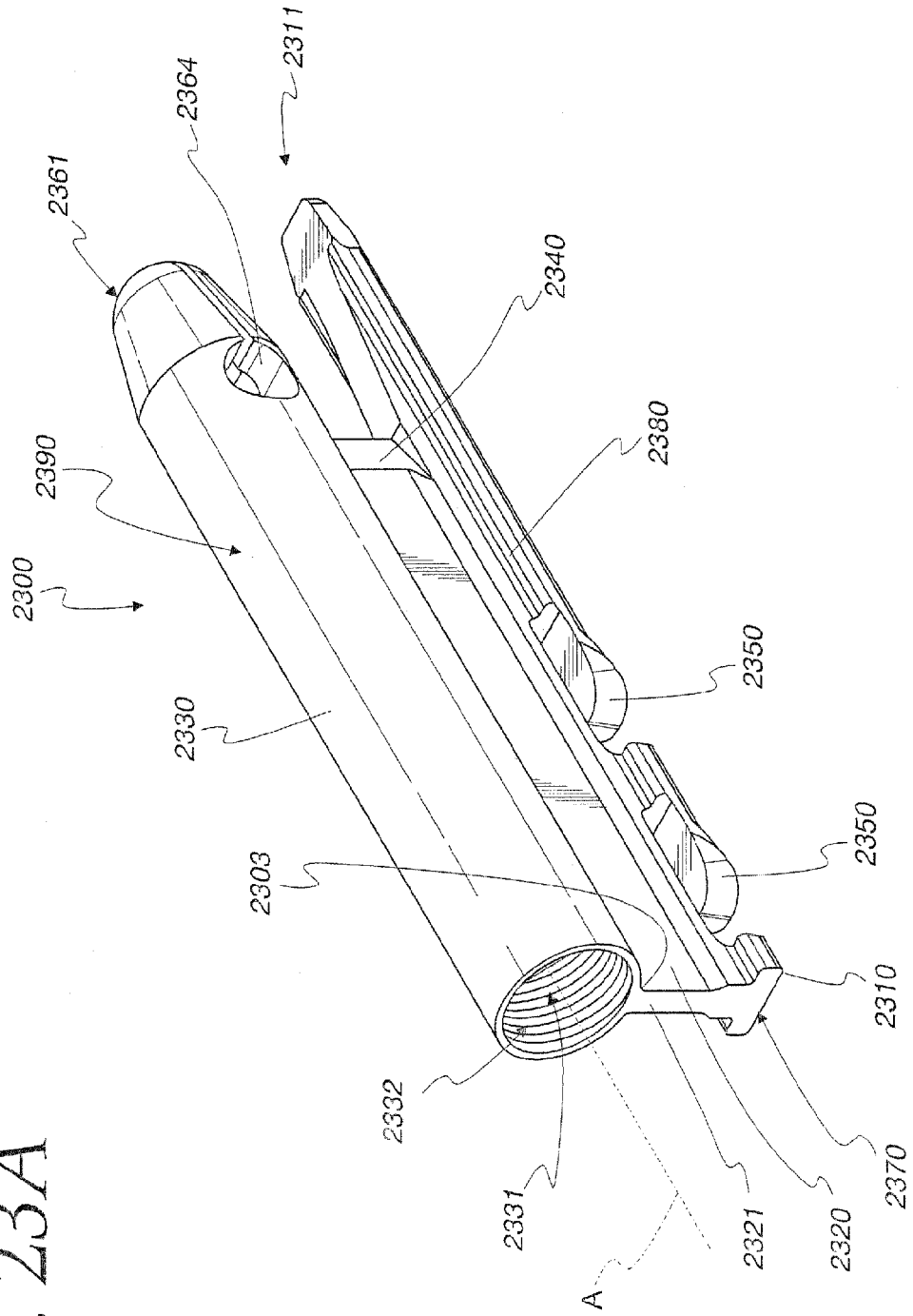
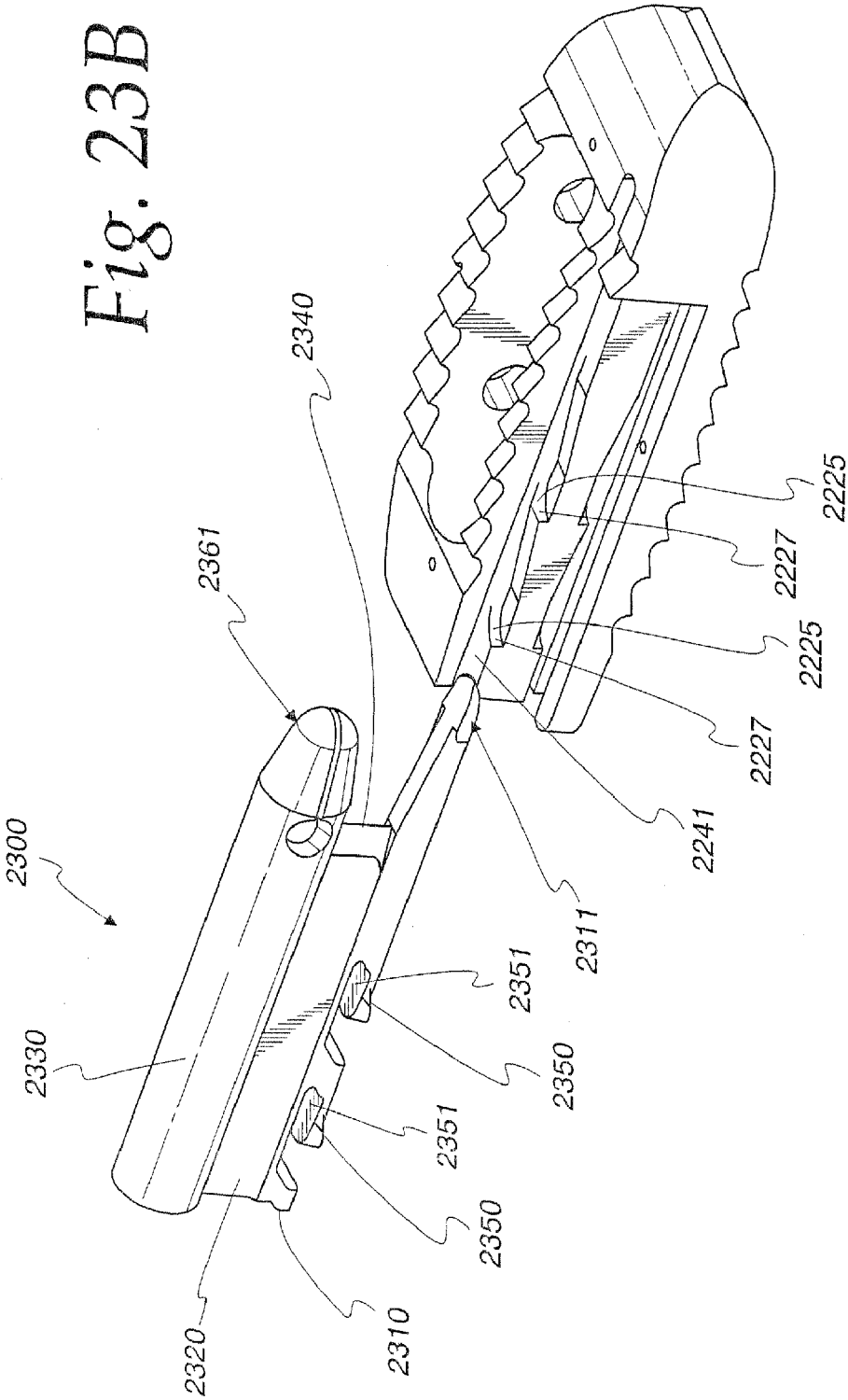


Fig. 23B



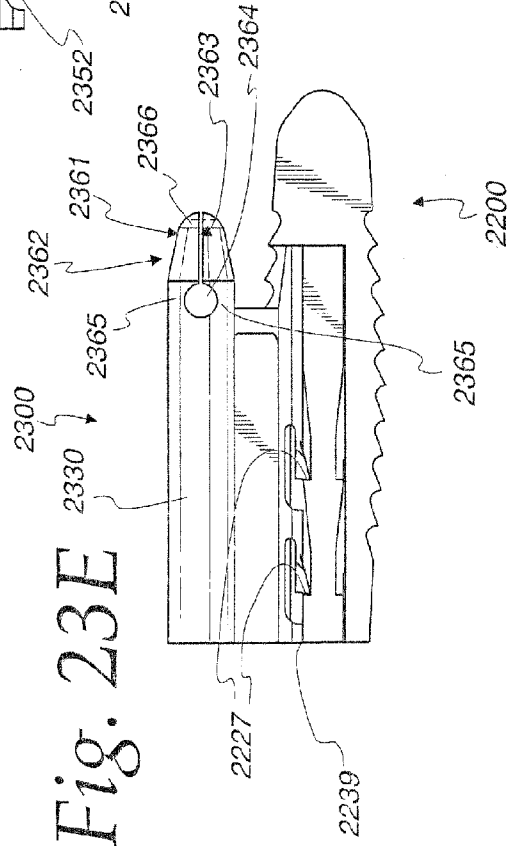
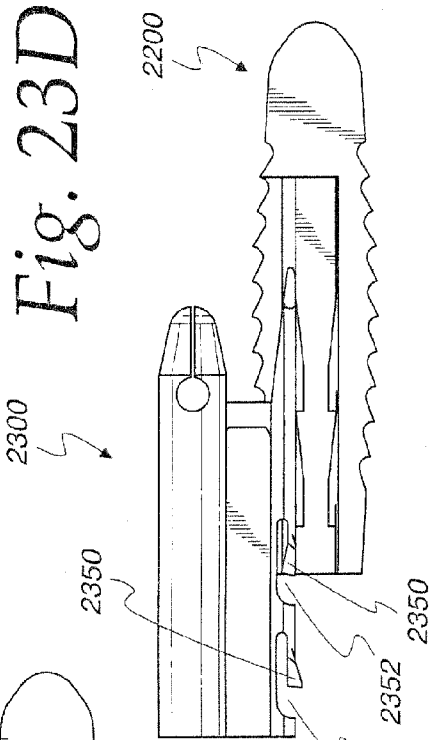
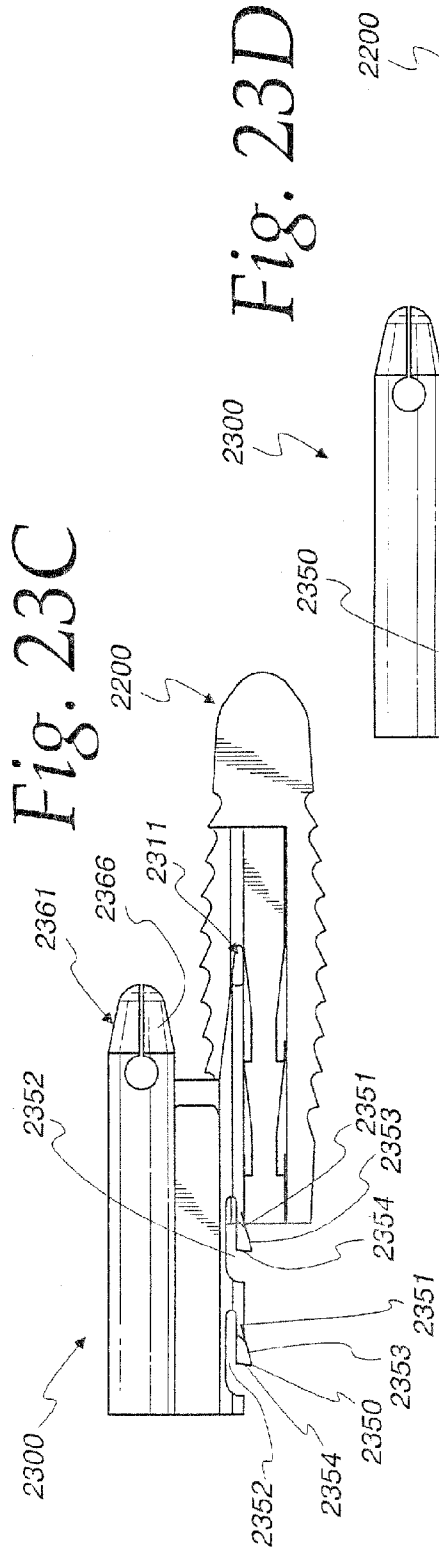


Fig. 23C

Fig. 23D

Fig. 23E

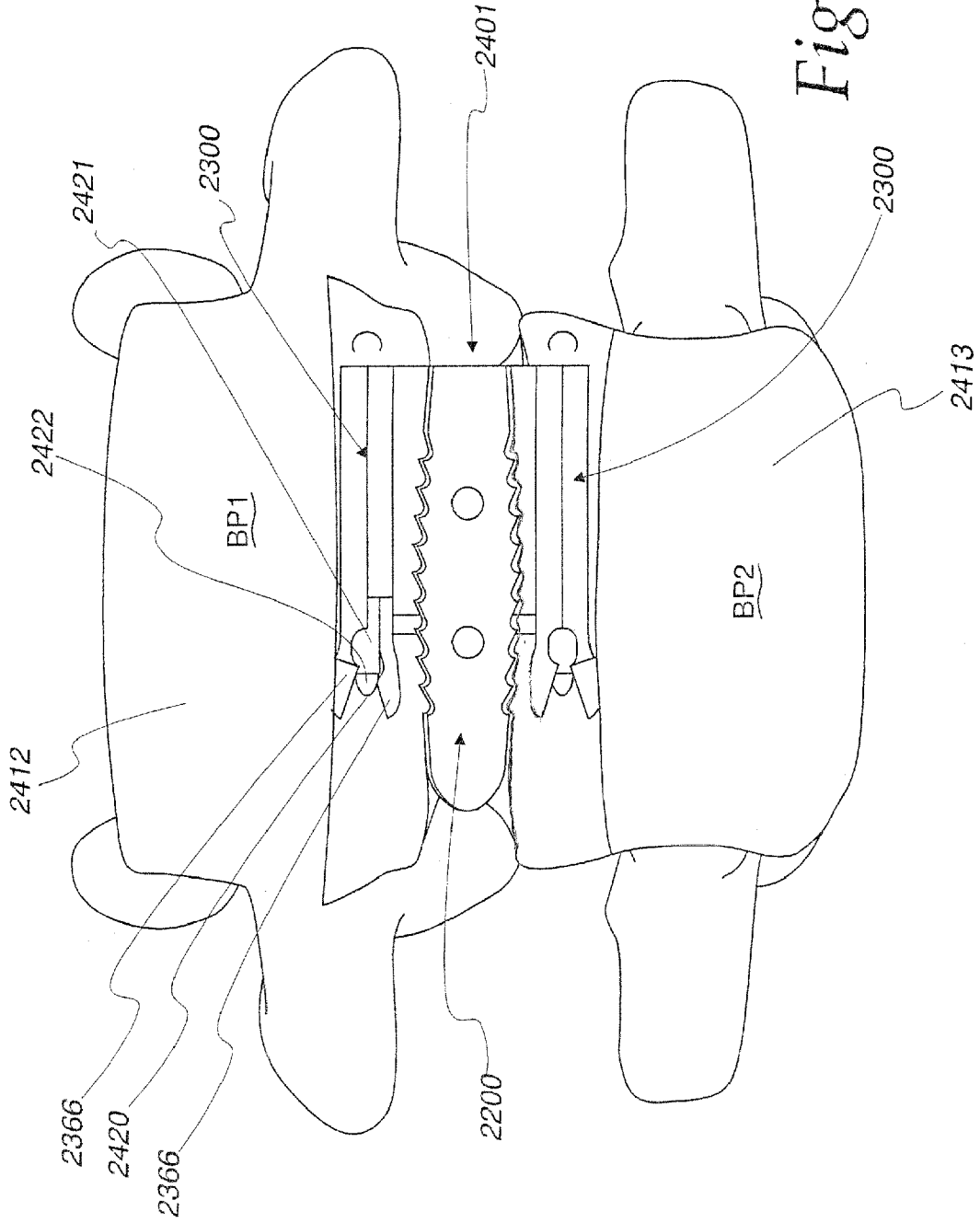


Fig. 24A

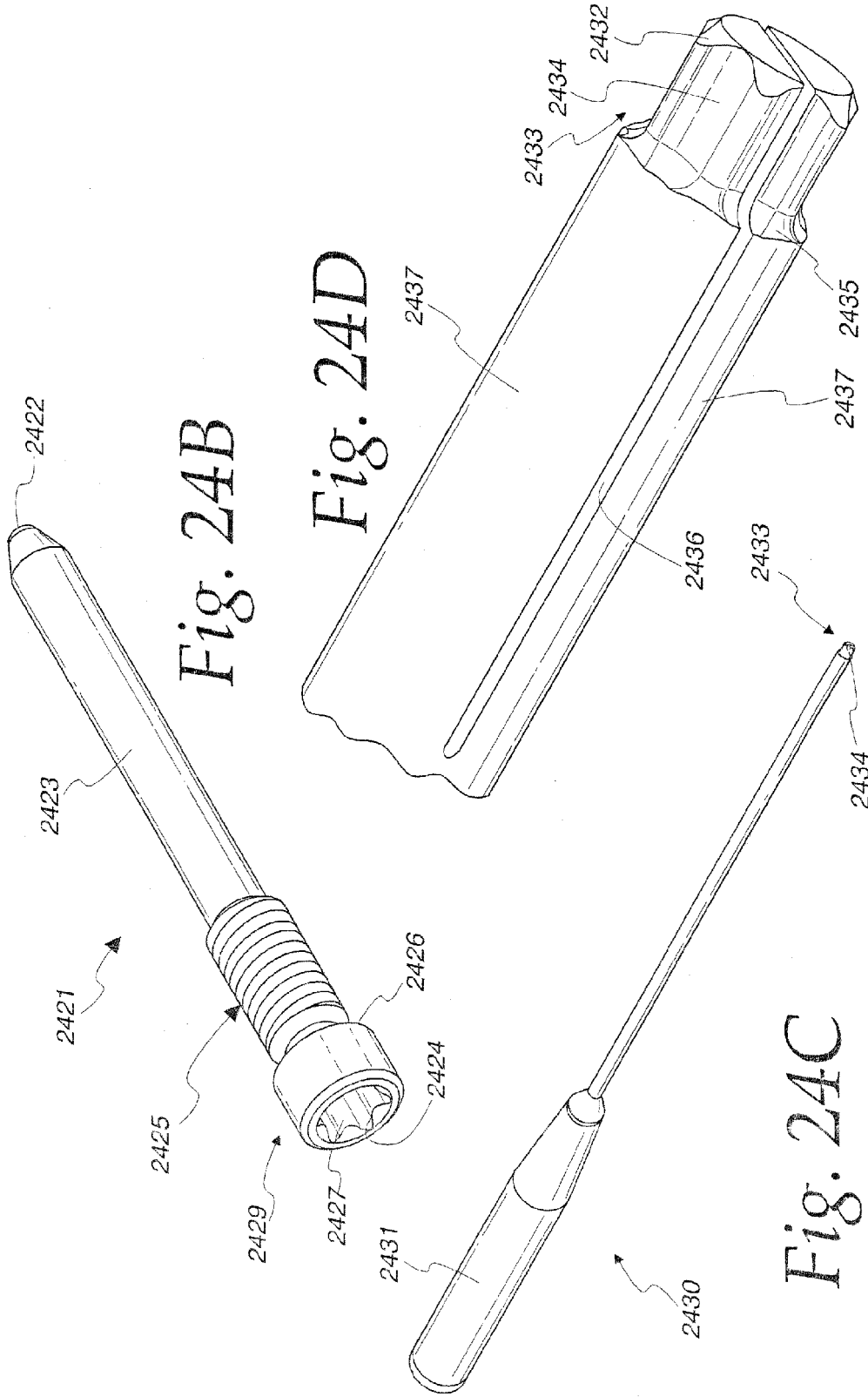


Fig. 25A

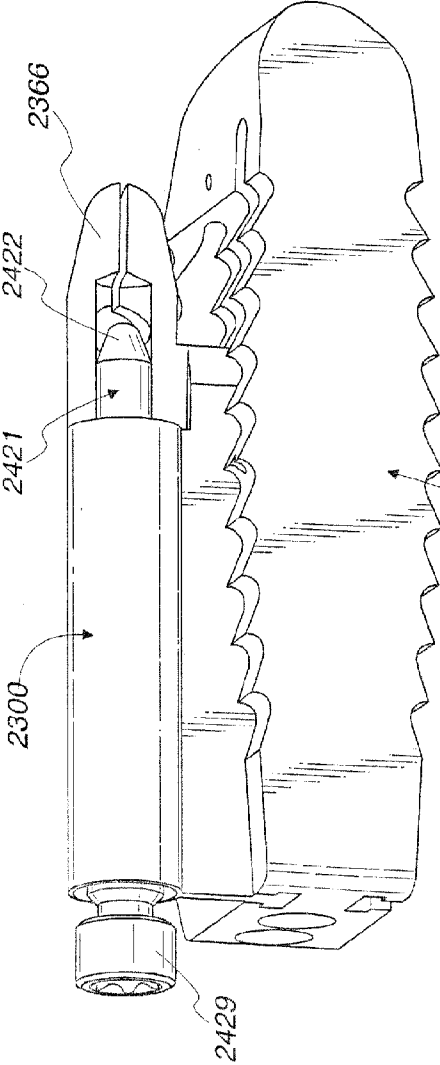


Fig. 25B

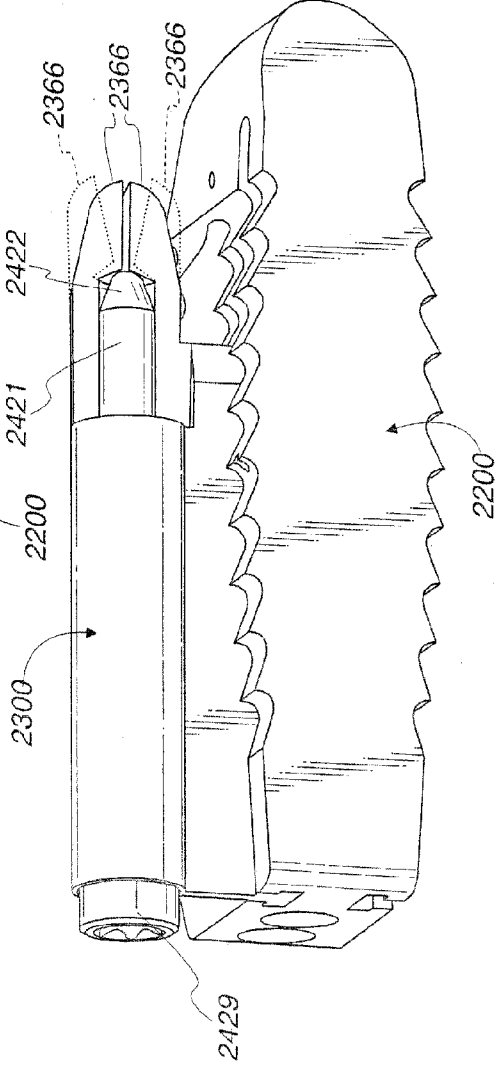


Fig. 26A

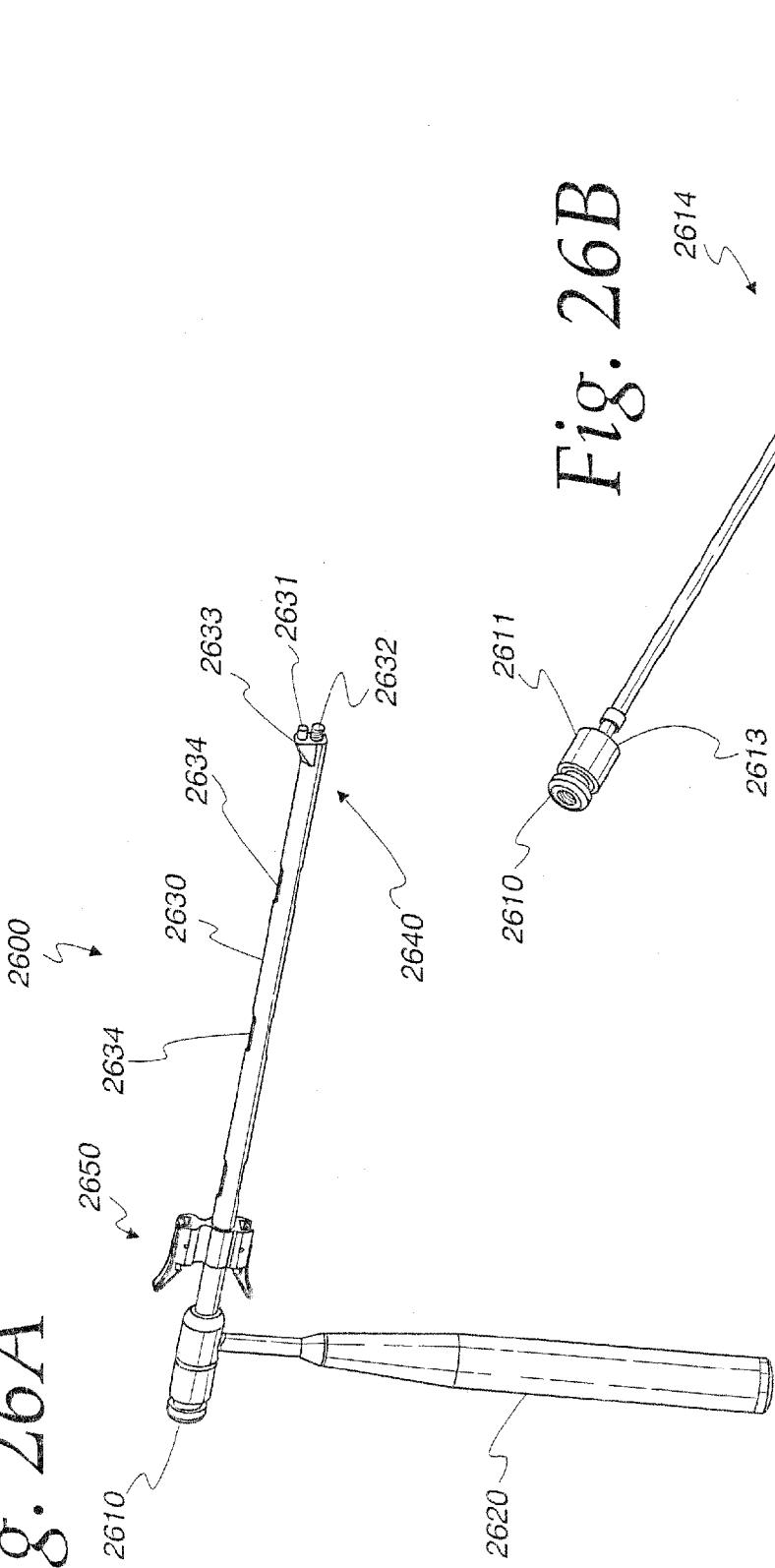


Fig. 26B

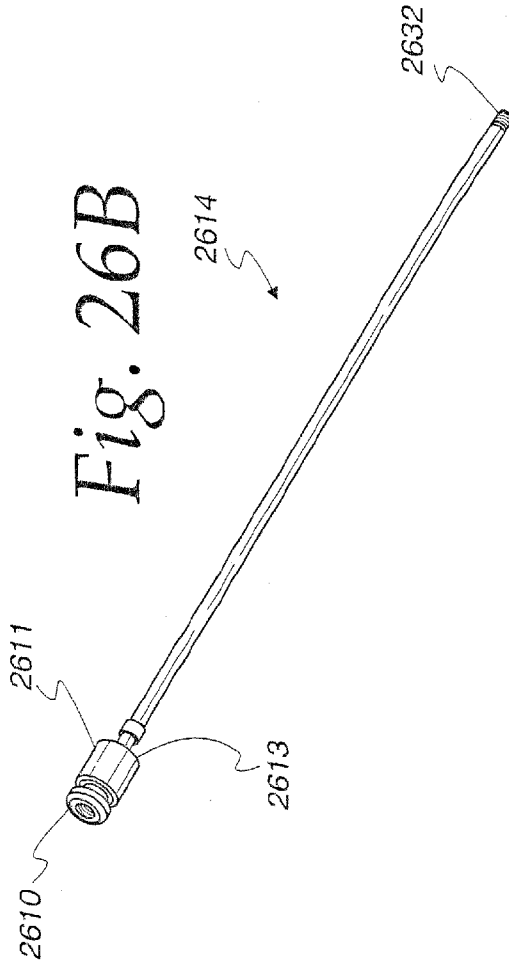


Fig. 26C

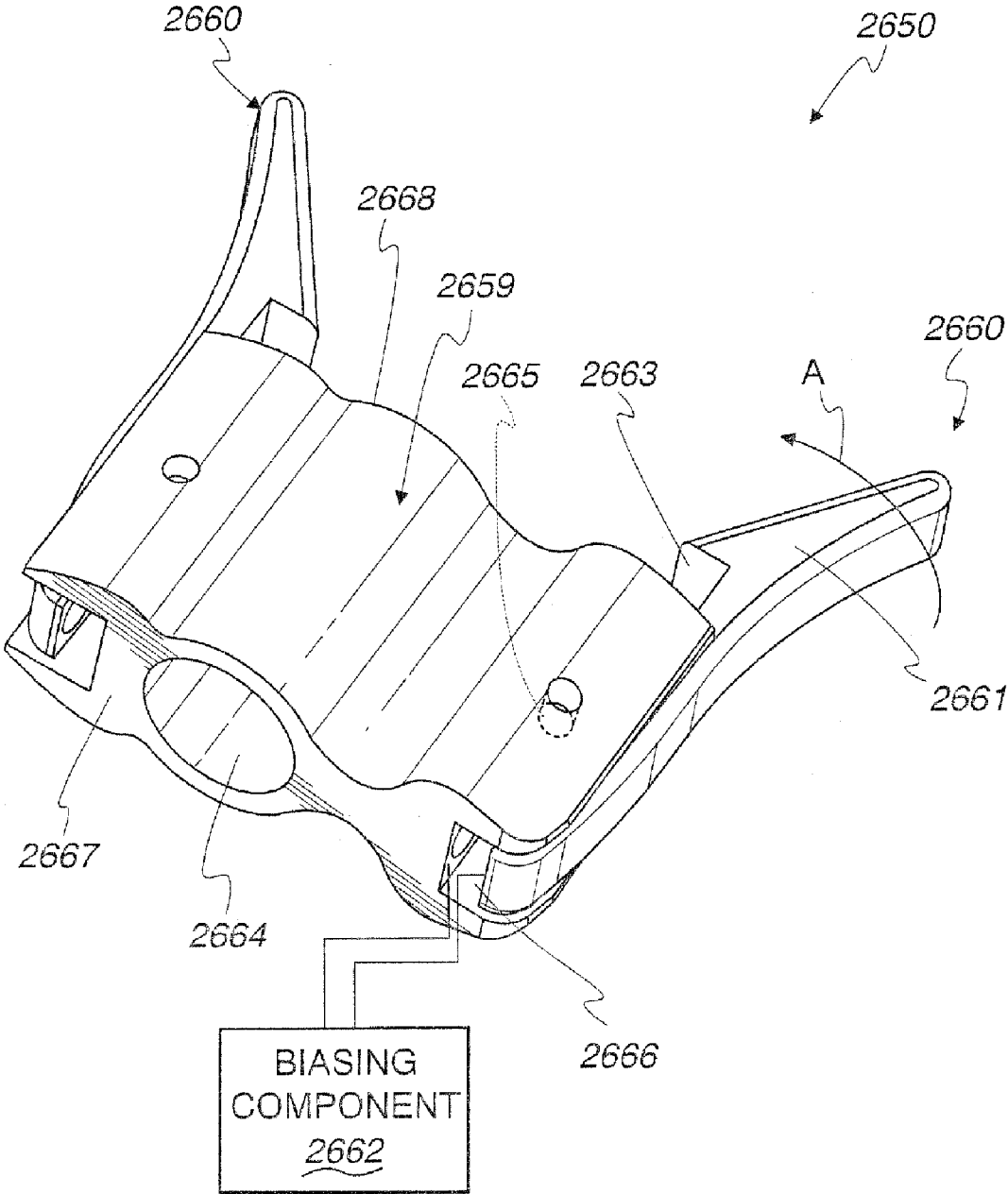
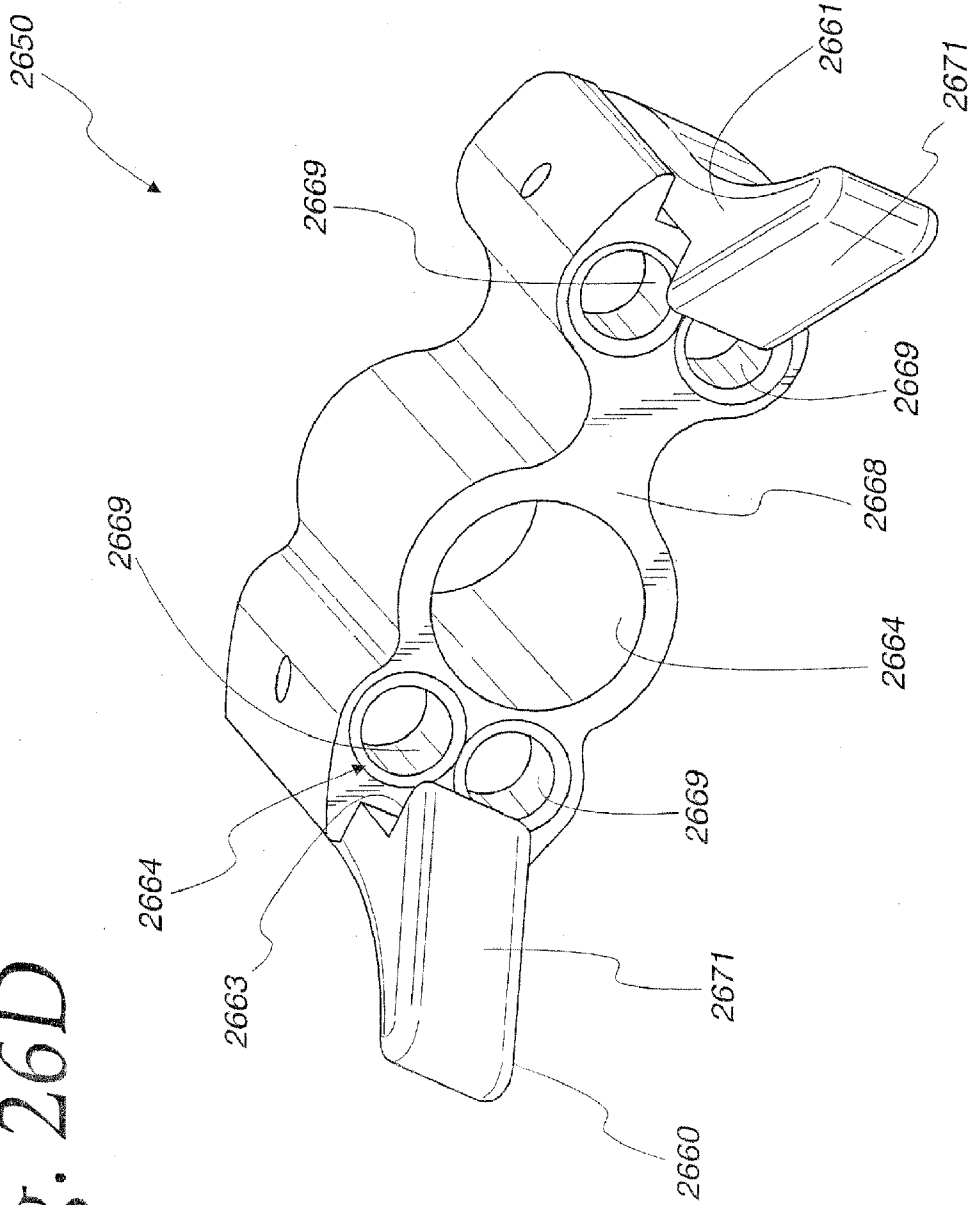


Fig. 26D



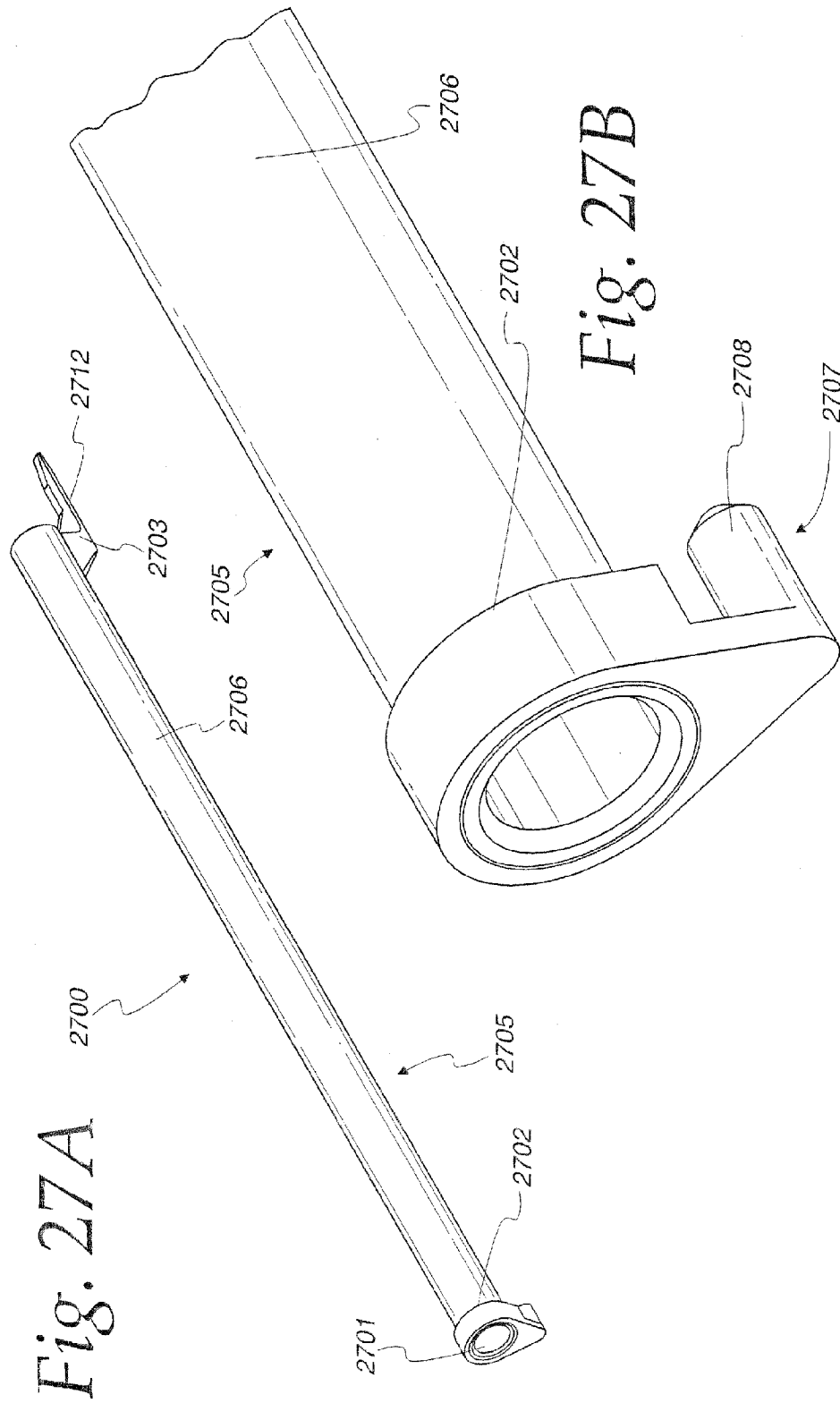


Fig. 27C

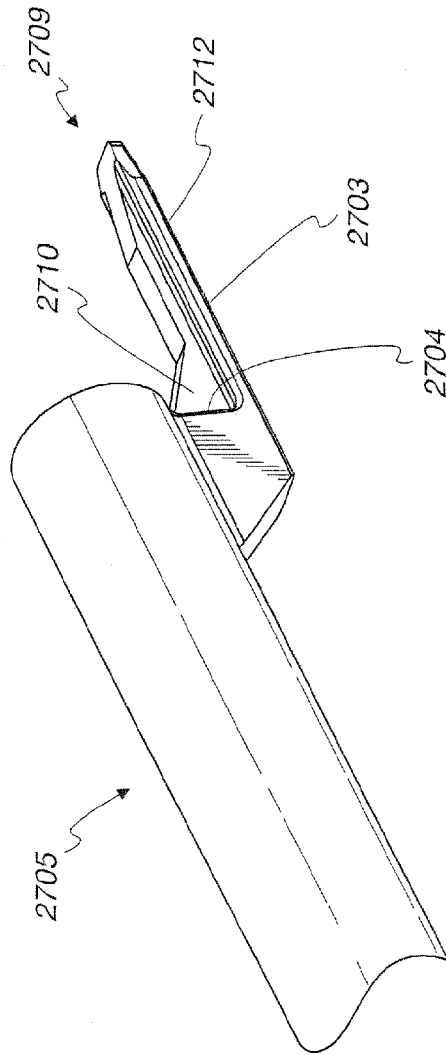
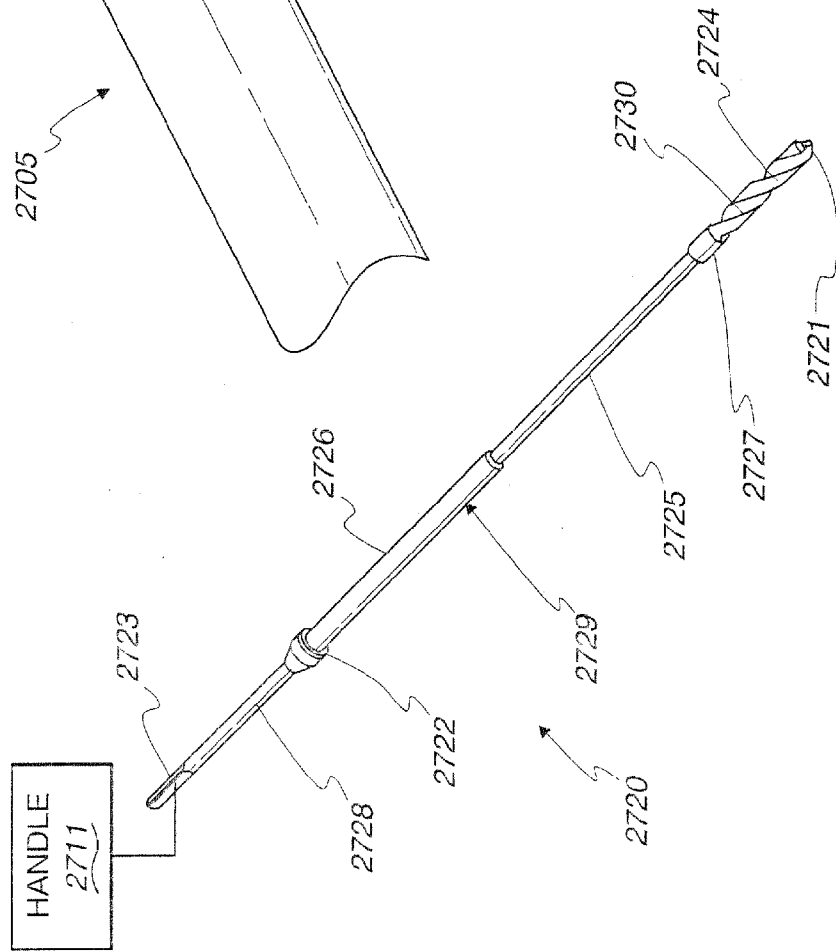


Fig. 27D



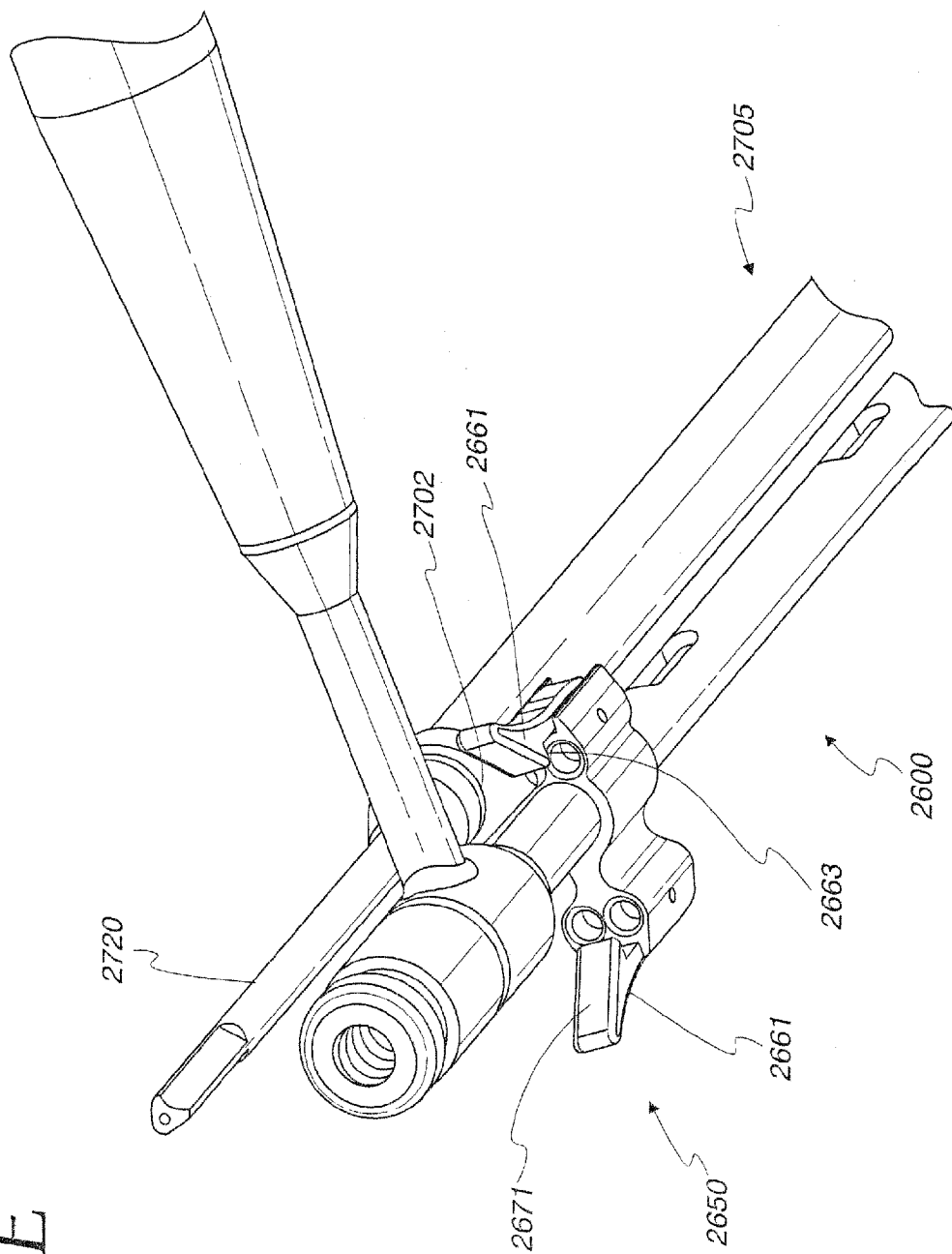


Fig. 27E

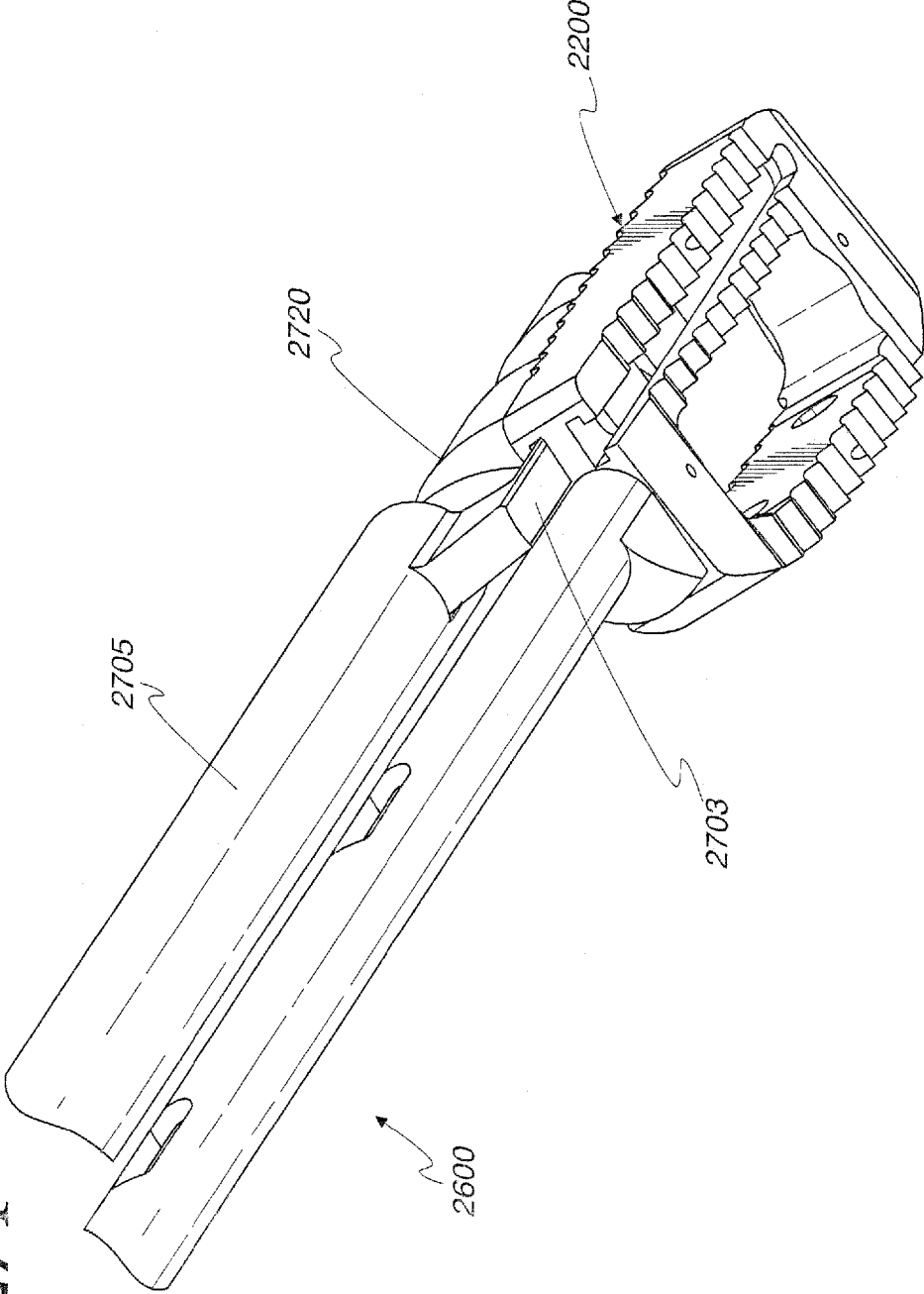


Fig. 27F

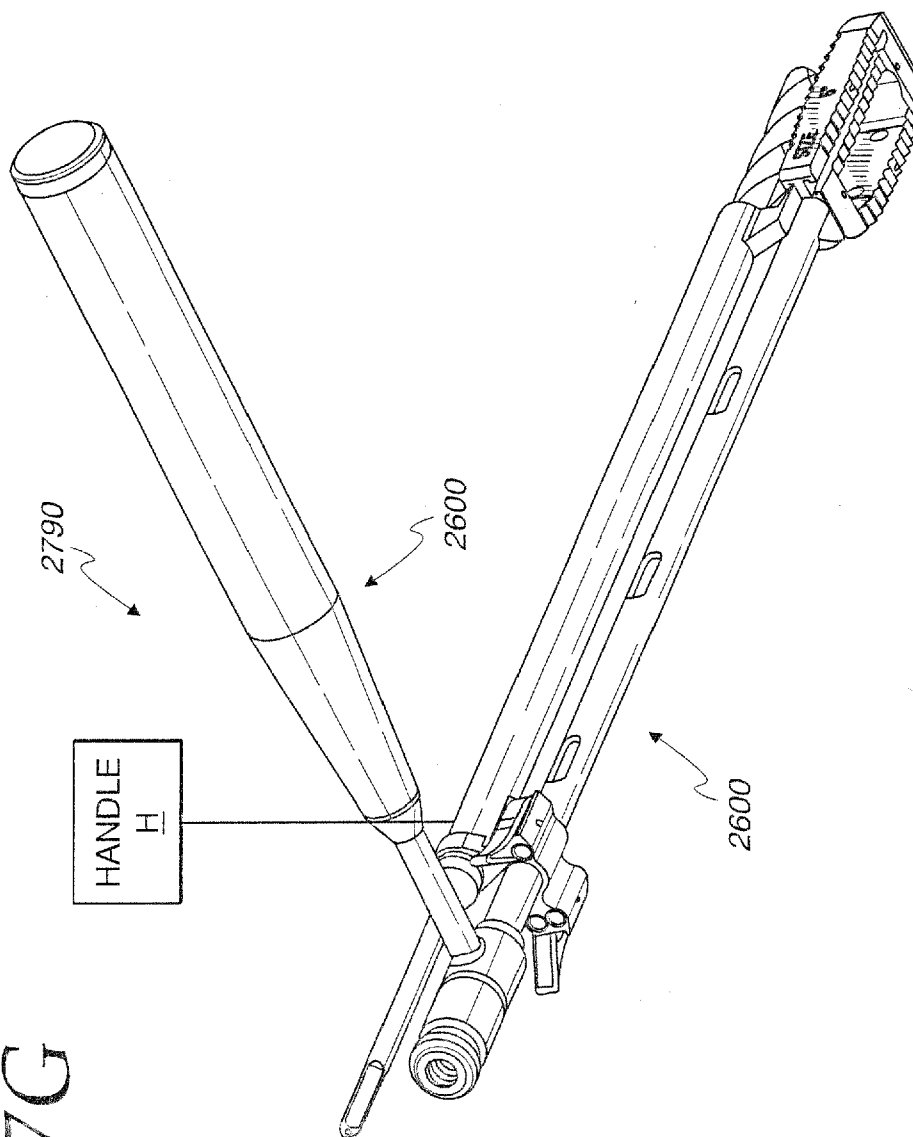
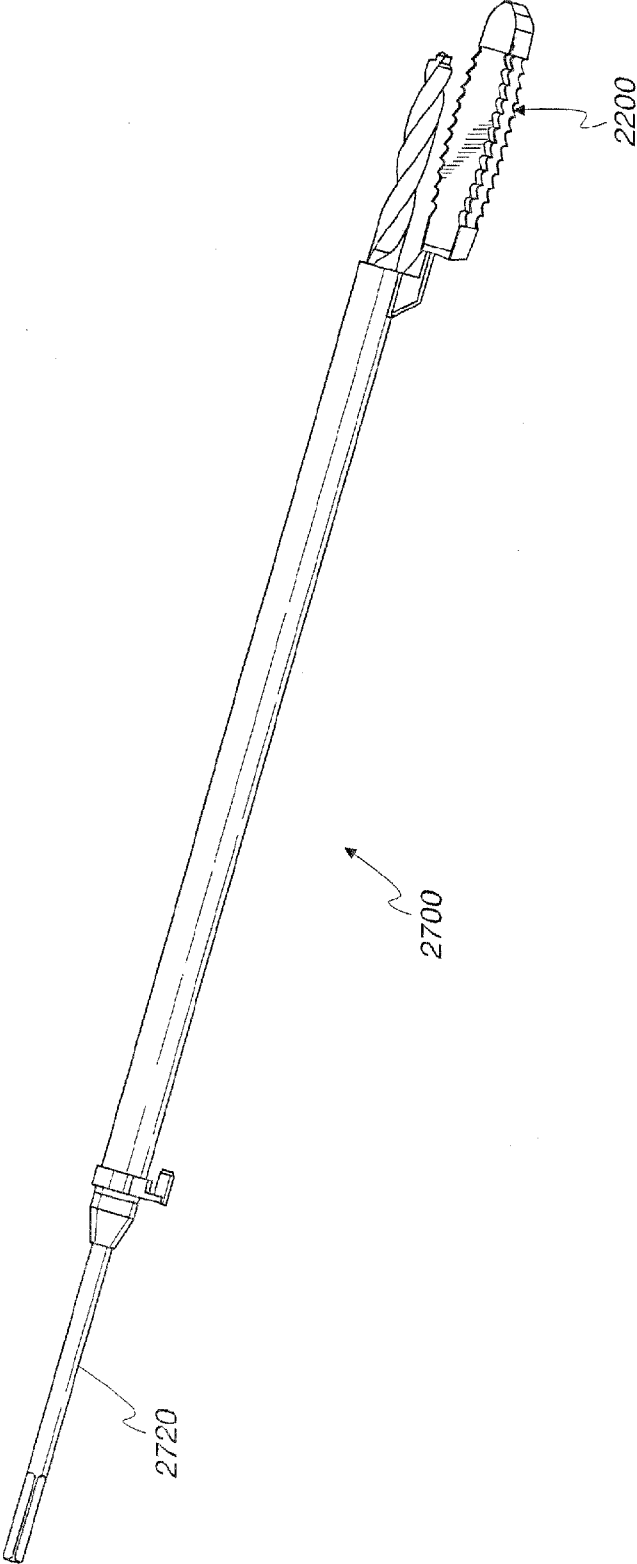


Fig. 27G

Fig. 27H



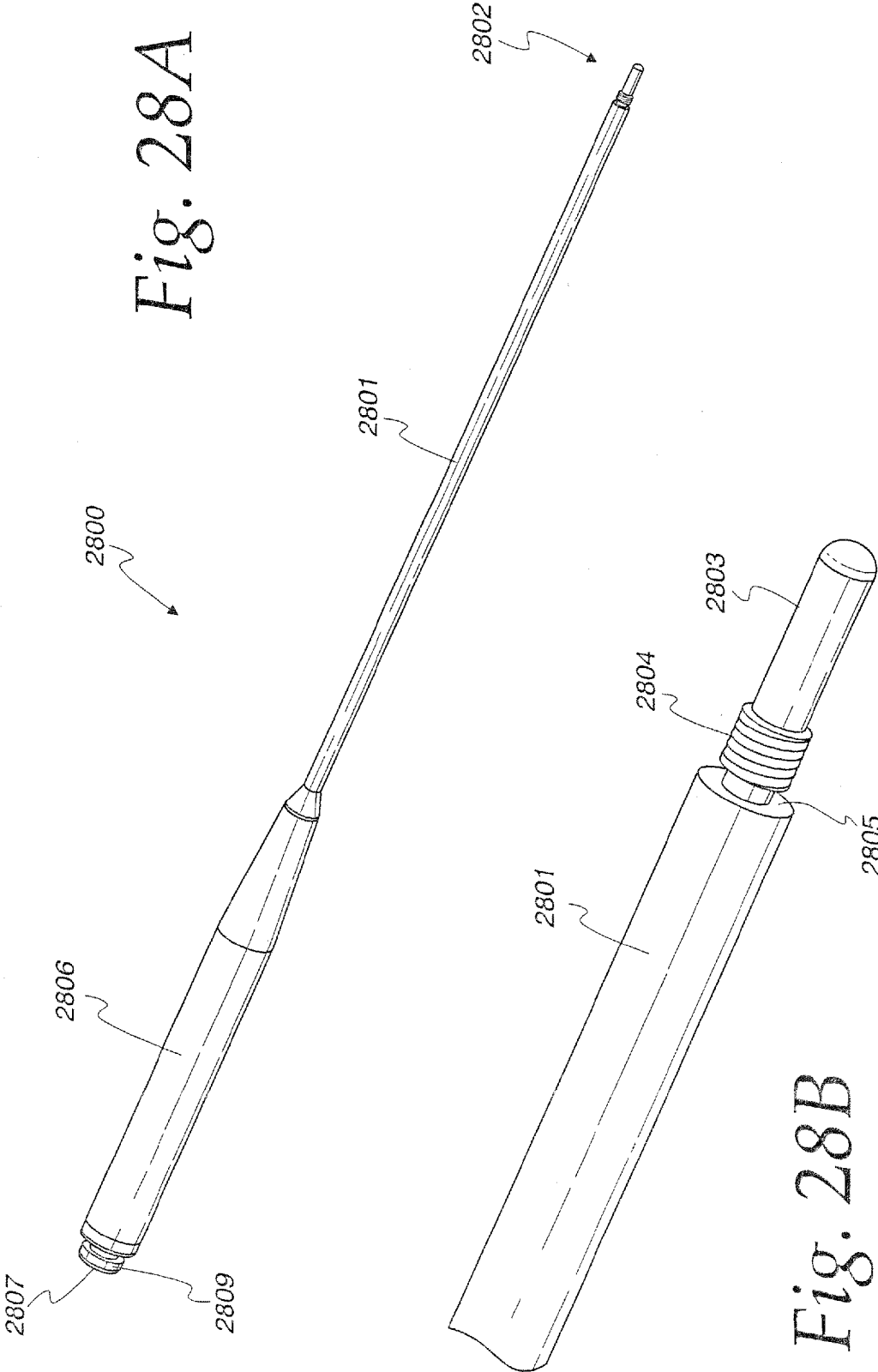


Fig. 28A

Fig. 28B

APPARATUS AND METHOD FOR STABILIZING ADJACENT BONE PORTIONS

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates generally to the stabilization of adjacent bone portions, and more particularly to an apparatus for securing interbody spacers between the adjacent bone portions. The invention is also directed to a method for stabilizing the adjacent bone portions.

[0003] 2. Background Art

[0004] Many different medical procedures are performed that require the stabilization of adjacent bone portions through the securing of an interbody spacer to the adjacent bone portions. Examples of these spacers are those known in the field as interbody cages, corpectomy cages, osteotomy wedges, joint spacers, bone void fillers, etc.

[0005] As one example, spacers are used to fuse joints. Spacers are also used to repair complex fractures where bone is missing and in bone regions where there are otherwise voids, as when a tumor and adjacent bone are removed. Spacers are also used in the performance of osteotomies by placing the spacers between adjacent bone portions to perform a wedging action, as to straighten a bone. This list is not exhaustive of the medical procedures that require the placement of a spacer between adjacent bone portions.

[0006] In each procedure, the spacer placed between the bone portions is required to be rigidly joined to the adjacent bone portions. A multitude of different apparatus have been devised for this purpose, with many requiring the insertion of screws. While screws are generally effective for this purpose, they are limited in the sense that they do not afford stability in all dimensions required to effect the optimal or desired rigidity.

[0007] Spacers are commonly used in spinal repair and reconstruction. The spine is a flexible column formed of a plurality of bones called vertebrae. The vertebrae are hollow and piled one upon the other, forming a strong hollow column for support of the cranium and trunk. The hollow core of the spine houses and protects the nerves of the spinal cord. The different vertebrae are connected to one another by means of articular processes and intervertebral, fibro-cartilaginous bodies.

[0008] The intervertebral fibro-cartilages are also known as intervertebral disks and are made of a fibrous ring filled with pulpy material. The disks function as spinal shock absorbers and also cooperate with synovial joints to facilitate movement and maintain flexibility of the spine. When one or more disks degenerate through accident or disease, nerves passing near the affected area may be compressed and are consequently irritated. The result may be chronic and/or debilitating back pain. Various methods and apparatus have been designed to relieve such back pain, including spinal fusion using a suitable graft or interbody spacer using techniques such as Anterior Lumbar Interbody Fusion (ALIF), Posterior Lumbar Interbody Fusion (PLIF), or Transforaminal Lumbar Interbody Fusion (TLIF) surgical techniques. The implants used in these techniques, also commonly referred to as vertebral body replacement (VBR) devices, are placed in the interdiscal space between adjacent vertebrae of the spine.

[0009] Ideally, a fusion graft should stabilize the intervertebral space and become fused to adjacent vertebrae. Moreover, during the time it takes for fusion to occur, the graft should have sufficient structural integrity to withstand the

stress of maintaining the space without substantially degrading or deforming and have sufficient stability to remain securely in place prior to actual bone ingrowth fusion.

[0010] One significant challenge to providing fusion graft stability (prior to actual bone ingrowth fusion) is preventing spinal extension during patient movement. Distraction of the vertebral space containing the fusion graft may cause the graft to shift or move, disrupting bone ingrowth fusion and causing pain.

[0011] Generally, existing spinal fusion technology has been limited or lacking in certain respects. Among the limitations of certain of these systems is the requirement that complicated steps be performed to effect their use. Others of these systems lack the optimal multi-dimensional stability, while others are less than desirable because they utilize components that project to externally of one or more of the bone portions between which the spacer is located.

[0012] The systems that rely upon the use of screws normally have such limitations. Generally these systems do not effectively allow compression forces to be generated between the spacers and adjacent bone portions. Further, while the screws stabilize the bone-spacer junction in one plane, that is normally flexion-extension, they do not control bending in planes orthogonal to the plane of the screw, that is normally side-to-side bending.

[0013] A further problem with existing systems is that parts typically are not locked and are thus prone to working loose. Screws, for example, may loosen over time in the absence of incorporating some structure that effectively prevents turning or lengthwise movement that results in partial or full separation from the bone portions and/or spacers that they penetrate.

[0014] The medical field is constantly seeking system designs that might be efficiently and consistently installed and that, most significantly, will effect the desired fusion in a manner that will be safe and reliable for the patient.

SUMMARY OF THE INVENTION

[0015] In one form, the invention is directed to a method for stabilizing first and second adjacent bone portions. The method includes the steps of: providing a spacer; providing a stabilizer, with the spacer and stabilizer configured to be movable guidingly, one relative to the other, between a pre-assembly relationship and an operative relationship; and placing the spacer and stabilizer into an operative relationship with the first and second adjacent bone portions by: a) placing the spacer between the first and second adjacent bone portions; b) directing the stabilizer into the first bone portion; and c) changing the spacer and stabilizer from their pre-assembly relationship into their operative relationship. As an incident of the spacer and stabilizer being changed from their pre-assembly relationship into the operative relationship with each other and the first and second bone portions, the spacer, stabilizer and first bone portion cooperate to cause the first bone portion and spacer to be urged towards each other.

[0016] In one form, the step of providing a stabilizer involves providing a stabilizer with a body having first and second spaced walls joined by a web. The first and second spaced walls respectively have first and second surfaces that face each other.

[0017] In one form, the method further includes the step of pre-forming a first channel in the first bone portion and the step of directing the stabilizer into the first bone portion involves moving the second wall guidingly in the first channel between a first position and a second position. The second

wall is in the second position with the spacer and stabilizer in the operative relationship with the first and second adjacent bone portions.

[0018] In one form, the spacer has a first surface that faces a first surface on the first bone portion with the spacer between the first and second bone portions and the stabilizer web has a sharp leading edge. The step of directing the stabilizer into the first bone portion includes the step of causing the sharp leading edge on the web to cut through the first bone portion between the first channel and first surface on the first bone portion.

[0019] In one form, the step of providing a stabilizer involves providing a stabilizer having a length, with the second wall having a lengthwise axis. The second surface has a convex curvature, as seen in cross-section taken transversely to the length of the stabilizer, with a radius at or adjacent to the lengthwise axis of the second wall. The stabilizer further has a leading end and a nose with a tapered surface portion that is angled between the leading end and the second surface. The spacer is placed between the first and second bone portions before the stabilizer is directed into the first bone portion. As an incident of the stabilizer being changed from its first position into its second position, the tapered nose surface bears against the first bone portion and progressively wedges the first bone portion towards the spacer.

[0020] In one form, the first and second bone portions are adjacent first and second vertebrae. The spacer has oppositely facing first and second surfaces. The first vertebra has a first endplate with a first surface facing the first surface on the spacer. The first endplate has a first dimension parallel to the length of the stabilizer with the spacer and stabilizer in their operative relationship. The step of providing a stabilizer involves providing a stabilizer wherein the second surface on the stabilizer applies a force on the first bone portion over a majority of the first dimension of the first surface of the first endplate that urges the first endplate surface against the first spacer surface.

[0021] In one form, the step of placing the spacer and stabilizer into operative relationship with the first and second adjacent bone portions involves causing a part of the first bone portion and a part of the spacer to be compressively maintained between the first and second stabilizer surfaces.

[0022] In one form, the step of directing the stabilizer into the first bone portion involves advancing the stabilizer guidingly in a path in a first direction. The method further includes the step of reconfiguring the stabilizer, with the spacer and stabilizer in the operative relationship with the first and second adjacent bone portions, into a locked state to block movement of the stabilizer relative to the first bone portion oppositely to the first direction.

[0023] In one form, the stabilizer has a first tab and the step of reconfiguring the stabilizer from the first state into the locked state involves moving the first tab from a first position into a second position wherein the first tab bears against the first bone portion.

[0024] In one form, the step of providing a stabilizer involves providing a stabilizer with a movable spreader, and the step of reconfiguring the stabilizer involves moving the spreader from a first position into a second position as an incident of which the first tab is moved from its first position into its second position.

[0025] In one form, the step of providing a stabilizer involves providing a stabilizer that is turned about an axis relative to the second wall to change the spreader between its first and second positions.

[0026] In one form, the first tab has a hinge portion and the step of moving the tab involves moving the tab about the hinge portion from its first position into its second position.

[0027] In one form, the first tab has a live hinge and the step of moving the first tab involves moving the tab about the live hinge portion from its first position into its second position.

[0028] In one form, the step of providing a stabilizer involves providing a stabilizer with first and second movable tabs, and the step of reconfiguring the stabilizer from the first state into the locked state involves moving the first tab from a first position into a second position wherein the first tab bears against the first bone portion. The second tab defines the tapered nose surface portion.

[0029] In one form, the step of providing a stabilizer involves providing a stabilizer with a movable spreader, and the step of reconfiguring the stabilizer involves moving the spreader from a first position into a second position, as an incident of which the first tab is moved from its first position into its second position and the second tab is moved from a first position into a second position.

[0030] In one form, the step of moving the spreader involves moving the spreader from its first position into its second position and against each of the first and second tabs to change each of the first and second tabs from its first position into its second position.

[0031] In one form, the step of providing a spacer involves providing a spacer with a channel and the step of changing the spacer and stabilizer from their pre-assembly relationship into their operative relationship involves moving a part of the stabilizer guidingly within the channel.

[0032] In one form, the steps of providing a spacer and stabilizer involve providing a spacer and stabilizer each with a blocking surface, which blocking surfaces abut to block the spacer and stabilizer from moving out of their operative relationship.

[0033] In one form, the steps of providing a spacer and stabilizer involve providing a spacer and stabilizer each with a blocking surface, which blocking surfaces are brought into confronting relationship as an incident of the spacer and stabilizer being changed from their pre-assembly relationship into their operative relationship.

[0034] In one form, the method further includes the step of reconfiguring one of the spacer and stabilizer with the spacer and stabilizer in their operative relationship to thereby place the blocking surfaces on each of the spacer and stabilizer in confronting relationship.

[0035] In one form, the steps of providing a spacer and stabilizer involve providing a deflectable tab defining the blocking surface on one of the spacer and stabilizer which deflects in one direction as the spacer and stabilizer are changed from their pre-assembly relationship into their operative relationship and is moved oppositely to the one direction under a restoring force to place the blocking surface on the one of the spacer and stabilizer into confronting relationship with the blocking surface on the other of the spacer and stabilizer as an incident of the spacer and stabilizer realizing the operative relationship.

[0036] In one form, the step of providing a stabilizer involves providing a stabilizer wherein the deflectable tab is on the first wall of the stabilizer.

[0037] In one form, the step of providing a stabilizer involves providing a stabilizer wherein the first wall and web on the stabilizer cooperatively define a “T”-shaped portion.

[0038] In one form, the step of providing a spacer involves providing a spacer with a “T”-shaped channel that is complementary to the “T”-shaped portion of the stabilizer, and the step of changing the spacer and stabilizer from their pre-assembly relationship into their operative relationship involves moving the “T”-shaped portion of the stabilizer guidingly within the “T”-shaped channel.

[0039] In one form, the step of providing a stabilizer involves providing a stabilizer with the second surface on the second wall having a convexly curved shape.

[0040] In one form, the step of providing a stabilizer involves providing a stabilizer with the second wall on the stabilizer having a cylindrical shape.

[0041] In one form, the step of providing a stabilizer involves providing a stabilizer wherein the first wall and web are substantially flat and cooperatively define a “T”-shaped portion. The second surface on the second wall has a convexly curved shape.

[0042] In one form, the method further involves the step of reconfiguring the stabilizer from a first state, with the spacer and stabilizer in the operative relationship with the first and second adjacent bone portions, into a locked state by moving a part of the stabilizer forcibly against the first bone portion.

[0043] In one form, the stabilizer is directed into the bone portion before the spacer and stabilizer are changed from their pre-assembly relationship into their operative relationship.

[0044] In one form, the method further includes the step of providing a second stabilizer and connecting the second stabilizer to each of the spacer and the second bone portion.

[0045] In one form, the method further includes the step of reconfiguring the stabilizer after it has been changed into the locked state back into the first state and thereafter separating the stabilizer and spacer from the first and second bone portions.

[0046] In one form, the method further includes the steps of providing a guide structure on the spacer and using the guide structure to pre-form the first channel in the first bone portion.

[0047] In one form, the step of moving the part of the stabilizer forcibly against the first bone portion involves the step of moving the part of the stabilizer forcibly against the first bone portion in a manner so as to thereby urge the first bone portion and spacer against each other.

[0048] In one form, the step of providing a spacer involves providing a spacer with first and second spaced bores. The method further includes the step of providing an auxiliary tool that is used in conjunction with the spacer by connecting the auxiliary tool using at least one of the first and second bores.

[0049] In one form, the method further includes the step of connecting the auxiliary tool to the spacer by placing first and second connectors on the auxiliary tool one each into the first and second bores.

[0050] In one form, the method further includes the step of connecting the auxiliary tool to the spacer by using either one, but only one, of the first and second bores.

[0051] In one form, the steps of providing a spacer and stabilizer include providing first and second deflectable tabs each defining a blocking surface on at least one of the spacer and stabilizer that each deflects in a direction as the spacer and stabilizer are changed from the pre-assembly relationship into the operative relationship, and are moved oppositely to

their deflecting direction under restoring forces to place each of the blocking surfaces separately into confronting relationship with a blocking surface on the spacer or stabilizer as an incident of the spacer and stabilizer realizing the operative relationship.

[0052] In one form, the step of placing a spacer and stabilizer in operative relationship with the first and second bone portions involves moving the spacer and stabilizer substantially only in a single plane and parallel to a single line.

[0053] In one form, the invention is directed to the combination of a stabilizer and spacer. The spacer can be placed between first and second adjacent bone portions and has oppositely facing surfaces. The stabilizer is movable guidingly relative to the spacer in a first path in a first direction: a) from a position wherein the stabilizer is in a pre-assembly relationship with the spacer; and b) into a position wherein the stabilizer is in an operative relationship with the spacer. The stabilizer is capable of being directed in the first direction while being moved in the first path relative to the spacer into one of the first and second bone portions so as to urge a surface of the one bone portion forcibly against one of the spacer surfaces with the spacer and stabilizer in operative relationship with each other and the first and second adjacent bone portions. The stabilizer has a body including first and second spaced walls joined by a web. The first and second spaced walls respectively have first and second surfaces that face each other. The second wall has a leading end and a surface portion that is angled with respect to the first path to produce a wedging action against the one bone portion as the stabilizer is advanced in the first direction in the first path into the one bone portion. The wedging action causes a part of the one bone portion and a part of the spacer to be urged towards each other as the spacer and stabilizer are moved into operative relationship with each other and the first and second adjacent bone portions.

[0054] In one form, the stabilizer has a length and a lengthwise axis. The first path is substantially straight along a first line and the second surface has a convex curvature as seen in cross-section taken transverse to the length of the stabilizer with a radius that is centered on a line parallel to the lengthwise axis of the stabilizer.

[0055] In one form, the stabilizer has a nose defining the tapered surface portion that is angled with respect to the central axis of the stabilizer.

[0056] In one form, the second wall has a cylindrical shape and the nose defines the surface portion that tapers between a leading end of the second wall and the second surface.

[0057] In one form, the nose is split to define separate tabs. One of the tabs is selectively movable so that the one tab forcibly engages the one bone portion to change the stabilizer from a first state into a locked state to prevent movement of the stabilizer relative to the one bone portion with the spacer and stabilizer in operative relationship with each other and the first and second adjacent bone portions.

[0058] In one form, the combination further includes a spreader that is selectively movable relative to the stabilizer to thereby change the stabilizer from the first state into the locked state.

[0059] In one form, the first wall and web are substantially flat and cooperatively define a “T”-shaped portion. The spacer has a “T”-shaped channel that cooperates with the “T”-shaped portion of the stabilizer to guide relative movement between the pre-assembly and operative relationships.

[0060] In one form, the second wall has a substantially cylindrical shape that defines the second surface.

[0061] In one form, the first surface resides in a first plane and the cylindrical shape has a central axis. The first plane and central axis of the cylindrical shape are substantially parallel.

[0062] In one form, the first surface resides in a first plane and the cylindrical shape has a central axis and the first plane and central axis of the cylindrical shape are at an angle with respect to each other.

[0063] In one form, the spacer has a channel to guide the stabilizer as the spacer and stabilizer are relatively moved between their pre-assembly and operative relationships. The spacer has a stop portion that abuts the stabilizer moving in the first direction so that the spacer and stabilizer can be consistently placed in their operative relationship.

[0064] In one form, the spacer and stabilizer have cooperating blocking surfaces that abut to block the spacer and stabilizer from moving out of their operative relationship.

[0065] In one form, the blocking surfaces contact each other as an incident of the spacer and stabilizer realizing the assembly relationship.

[0066] In one form, one of the blocking surfaces is on a movable tab on one of the spacer and stabilizer. The movable tab is deflected in one direction as the spacer and stabilizer are moved from their pre-assembly relationship toward their operative relationship and moves under a restoring force oppositely to the one direction upon the operative relationship between the spacer and stabilizer being realized.

[0067] In one form, the second wall has a cylindrical shape with a central axis. The combination further includes a drill guide on the spacer and a drill that is movable controllably along the drill guide parallel to a central axis of the drill. The spacer has a third surface to which the first surface of the stabilizer abuts with the spacer and stabilizer in their operative relationship. A first distance between the central axis of the drill on the drill guide and the third surface is greater than a second distance between the central axis of the second wall and the first surface.

[0068] In one form, the first distance is greater than the second distance by on the order of 0.5 mm.

BRIEF DESCRIPTION OF THE DRAWINGS

[0069] FIG. 1 is a schematic, perspective view of one embodiment of an interbody spacer showing a superior surface and an anterior surface thereof;

[0070] FIG. 2 is a perspective view of one embodiment of a stabilizer;

[0071] FIG. 3 is an end view of the stabilizer of FIG. 2;

[0072] FIG. 4 is an end plan view of the spacer of FIG. 1 inserted between two vertebrae with the stabilizers of FIG. 2 anchoring the spacer to the vertebrae;

[0073] FIG. 5A is a top perspective view of another embodiment of a stabilizer;

[0074] FIG. 5B is an end view of the stabilizer of FIG. 5A;

[0075] FIGS. 6A-6J depict end views of multiple embodiments of different stabilizers;

[0076] FIG. 7 is an end view of one embodiment of a spacer with self-retaining clips;

[0077] FIGS. 8A-M depict various conventional embodiments of interbody spacers;

[0078] FIG. 9 is a schematic, perspective view of another embodiment of an interbody spacer showing a superior surface and an anterior surface thereof;

[0079] FIG. 10 is an end view of yet another embodiment of a stabilizer;

[0080] FIG. 11 is a perspective view of the stabilizer of FIG. 10;

[0081] FIG. 12 is an end view of the spacer of FIG. 9 with the two stabilizers according to FIG. 10 inserted into the spacer;

[0082] FIG. 13 is a schematic representation of an inventive system, including at least one bone portion/member with an interbody spacer fixed thereagainst utilizing a stabilizer;

[0083] FIG. 14 is a perspective view of a modified form of stabilizer, according to the invention;

[0084] FIG. 15 is a fragmentary, perspective view showing a spacer against a bone portion and a further modified form of stabilizer that is configured to urge the bone portion and spacer towards each other as the stabilizer is inserted;

[0085] FIG. 16 is a view as in FIG. 15 wherein a different configuration of stabilizer and spacer are used to perform as described for the corresponding components in FIG. 16;

[0086] FIG. 17 is a view as in FIGS. 15 and 16 showing a further modified form of stabilizer with one form of locking assembly to maintain the stabilizer in place;

[0087] FIG. 18 is an enlarged, plan view of a modified form of locking assembly on a stabilizer and spacer and with locking assembly components on the stabilizer configured as they would be with the locking assembly in a locked state;

[0088] FIG. 19 is a perspective view of a modified form of stabilizer and spacer, similar to that shown in FIG. 18, with a locking assembly thereon in an assembly state, the stabilizer aligned to be directed into the spacer and abutted bone portion and with a spreader element aligned to be directed into the stabilizer to change the locking assembly from the assembly state into a locked state;

[0089] FIG. 20 is an enlarged, fragmentary, plan view of the stabilizer in FIG. 19 with the locking assembly component on the stabilizer shown in solid lines as it is configured with the locking assembly in an assembly state and in dotted lines as it is configured with the locking assembly in the locked state;

[0090] FIG. 21 is an elevation view of a modified form of stabilizer joined with a spacer and bone portion with a locking tab secured against the bone portion with a fastener;

[0091] FIG. 22A is a perspective view of another embodiment of an interbody spacer showing an anterior, proximal, and superior surface thereof;

[0092] FIG. 22B is a perspective view of an embodiment of an interbody spacer illustrating a posterior, proximal, and superior surface thereof;

[0093] FIG. 22C is a side view of a spacer embodiment;

[0094] FIG. 22D is a top view of one embodiment of a spacer;

[0095] FIG. 23A is a perspective view of one embodiment of a stabilizer;

[0096] FIG. 23B is a perspective view of a stabilizer with its base nose just beginning to enter into a channel of a spacer, with a portion of the spacer resected for reviewing purposes;

[0097] FIG. 23C is a side view of a stabilizer as it begins to insert into the channel of a spacer, with a portion of the spacer resected for viewing purposes;

[0098] FIG. 23D is a side view of a stabilizer with self retaining clips deflecting into deflection pockets as the stabilizer is further translated into the spacer, with a portion of the spacer resected for viewing purposes;

[0099] FIG. 23E is a side view of a stabilizer fully docked within a spacer and self retaining clips fully seated within stop pocket, with a portion of the spacer resected for viewing purposes;

[0100] FIG. 24A is a front view of a spacer-stabilizer assembly installed within the intervertebral space, with the superior and inferior vertebral bodies partially resected for viewing of the deployed stabilizers as they would reside in the bone;

[0101] FIG. 24B is a perspective view of a spreader used to deploy the tabs of the stabilizer;

[0102] FIG. 24C is a perspective view of a spreader driver tool;

[0103] FIG. 24D is a close-up perspective view of a drive head of the spreader driver tool;

[0104] FIG. 25A is a perspective view of a spacer with a stabilizer docked therein, with a spreader partially seated within the stabilizer;

[0105] FIG. 25B is a perspective view of a spacer with a stabilizer docked therein, a spreader partially seated within the stabilizer wherein the nose of the spreader begins contact with the internal surface of the stabilizer tabs;

[0106] FIG. 26A is a perspective view of a spacer/cage inserter tool;

[0107] FIG. 26B is a perspective view of a locking shaft utilized inside the spacer/cage inserter tool for holding the spacer tight to the inserter tool;

[0108] FIG. 26C is a perspective view of an accessory guide holder illustrating a locking mechanism;

[0109] FIG. 26D is a perspective view of an accessory guide holder illustrating an opposing view of a locking mechanism;

[0110] FIG. 27A is a perspective view of a drill guide;

[0111] FIG. 27B is a perspective view of the proximal portion of a drill guide illustrating a positioner for docking with the spacer inserter tool;

[0112] FIG. 27C is a perspective view of the distal portion of a drill guide illustrating the drill guide tip;

[0113] FIG. 27D is a perspective view of a drill configured for use with a drill guide;

[0114] FIG. 27E is a perspective view of a drill guide body and drill docked with a spacer inserter tool;

[0115] FIG. 27F is a perspective view of the distal portion of a drill guide-spacer inserter assembly illustrating the interface between a tool and spacer;

[0116] FIG. 27G is a perspective view of a drill-guide spacer inserter assembly and drill secured to the spacer;

[0117] FIG. 27H is a perspective view of a drill guide docked to a spacer with drill fully inserted in the drill guide, with the spacer inserter tool hidden;

[0118] FIG. 28A is a perspective view of a stabilizer inserter; and

[0119] FIG. 28B is a close-up perspective view of the stabilizer inserter illustrated in FIG. 28A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0120] Embodiments of the invention will now be described with reference to the Figures, wherein like numerals reflect like elements throughout. The terminology used in the description presented herein is not intended to be interpreted in any limited or restrictive way, simply because it is being utilized in conjunction with detailed description of certain specific embodiments of the invention. Furthermore,

embodiments of the invention may include several novel features, no single one of which is solely responsible for its desirable attributes or which is essential to practicing the invention described herein.

[0121] FIG. 1 illustrates schematically one embodiment of an interbody spacer **100**. The spacer **100** can be used between any adjacent bone portions, such as members at a joint, in a void between such joint portions as might be developed by a fracture, through a procedure that removes bone as with a tumor, etc. While the invention is contemplated for use with virtually any adjacent bone portions between which a spacer is required, the initial disclosure herein will be directed towards spinal procedures wherein the spacer **100** is placed between adjacent vertebrae/joint members that make up a subset of the more generically referenced bone portions.

[0122] Embodiments of the invention can be incorporated in any number of interbody or vertebral body replacement devices, including for example, the devices shown in FIGS. **8A-8M**. All of the interbody spacer devices shown in FIGS. **8A-8M** are commercially available from Alphatec Spine™, Inc. (See website at: <http://www.alphatecspine.com/products/interbody.asp>). FIGS. **8A** and **8B** depict top perspective views of two configurations PA1, PA2 of the “Novel Cervical Interbody System” for use in an anterior cervical fusion procedure. FIGS. **8C-8F** show top perspective views of four different configurations PA3, PA4, PA5, PA6 of the “Novel CP Vertebral Body Replacement System” for use in the thoracolumbar spine (T1-L5). FIGS. **8G** and **8H** illustrate two “Novel VC Spinal Spacers” PA7, PA8 for use in Anterior Lumbar Interbody Fusion (ALIF), made of PEEK or titanium. FIGS. **8I** and **8J** depict two “Novel SD” interbody spacer devices PA9, PA10 made of PEEK or titanium, for use in a Posterior Lumbar Interbody Fusion (PLIF). FIGS. **8K** and **8L** show two “Novel LCC Spacer” devices PA11, PA12 made of PEEK and titanium, for use in a Posterior Lumbar Interbody Fusion (PLIF). FIG. **8M** illustrates a “Novel TL Spacer” device PA13 for use in a Transforaminal Lumbar Interbody Fusion (TLIF).

[0123] The spacer **100** is used in spinal fusion surgeries including ALIF, PLIF and TLIF procedures, wherein two or more vertebrae are joined or fused together for the treatment of spinal disorders such as spondylolisthesis, scoliosis, severe disc degeneration, or spinal fractures. The embodiments below are described primarily in the context of an ALIF procedure, though other spinal implants and procedures are also contemplated.

[0124] The spacer **100**, shown schematically in FIG. 1 and contemplated to have the shapes of any of the conventional spacers PA1-PA13, described above, or any other suitable shape, includes first and second opposite surfaces **120** and **130** respectively configured to engage superiorly and inferiorly the end plates of adjacent vertebrae. As shown for the spacers in FIGS. **8A-8M**, these corresponding surfaces PA20 and PA30 may have ridges, bumps or other protrusions PA35 to enhance engagement with the vertebral endplates. As also shown in FIGS. **8A-8M**, these surfaces PA20 may define openings PA40 (not shown in FIG. 1) to allow for fusion through the openings.

[0125] In the embodiment shown in FIG. 1, the first and second surfaces **120** and **130** are substantially flat and parallel. However, in other embodiments, the first and second surfaces can be angled relative to each other and may be non-flat, so as to better support adjacent vertebral bodies in a more natural spinal alignment configuration. For example,

the first and second opposite surfaces, PA20 and PA30 of the interbody spacer shown in FIG. 8A, are slightly angled toward each other in the direction of the posterior surface PA42. Additionally, the first and second opposite surfaces, PA20 and PA30 of the interbody spacers shown in FIGS. 8I and 8J, are tapered toward each other toward the ends PA44 of the interbody spacers.

[0126] The spacer 100 has a proximal face 140 and a distal face 150, the proximal face 140 corresponding to the end that engages a delivery tool, such as with grooves or indentations PA46 or a threaded opening PA48 as shown in FIGS. 8A-8M. For an ALIF procedure, the proximal face 140 corresponds to the anterior face of the spacer (such as the convex surface PA50 in FIGS. 8G and 8H), and the distal face 150 corresponds to the posterior face of the spacer (such as the flat surface PA52 in FIG. 8H).

[0127] As illustrated in FIG. 1, the spacer 100 has three channels 155 for receiving suitable complementary stabilizers (discussed in further detail below), although it is to be understood that in other embodiments the spacer can have only one channel and in yet other embodiments, the space can have any number of channels.

[0128] The channels 155 interface with the first and second surfaces 120 and 130 of the spacer 100, as well as with at least the proximal surface 140 of the spacer 100. The channels 155 shown in FIG. 1 are shown extending through the body of the spacer 100, and interfacing with the distal surface 150 of the spacer 100. However, in other embodiments, the channels do not extend all the way through the spacer body to interface with the distal surface of the spacer and in other embodiments the channels 155 can interface with side surfaces 160 and 170. The channels 155 are preferably pre-cut into the spacer body 100 before insertion into the vertebral space during surgery. Where the spacer 100 has openings in the surfaces 120 and 130, the channels 155 may extend through solid portions of the spacer between the openings (such as through the intermediate bar PA54 shown in FIG. 8G, or may be interrupted by the openings PA40 so that the channels are provided on opposite sides of the openings PA40).

[0129] The interbody spacer 100 can be made of a rigid and durable biocompatible material such as titanium, titanium alloy, stainless steel iron steel and compositions thereof. Additionally, or alternatively, non-metal biocompatible materials such as cadaveric bone, polymers, elastomers, resins, ceramics and composites thereof can be employed. In a preferred embodiment, the interbody spacer is made of Polyetheretherketone (PEEK).

[0130] FIGS. 2 and 3 illustrate one embodiment of a stabilizer 200 suitable for use with the spacer 100 of FIG. 1, where FIG. 3 is an end view of the stabilizer of FIG. 2. The stabilizer 200 is configured to be partially received within the channels 155 of the spacer 100, with a portion extending out of the channel away from the surface 120 or 130 into the adjacent vertebral body. The stabilizer 200 is preferably thin enough to slice through bone, yet strong enough to hold onto the bone and stabilize the spacer 100 after insertion.

[0131] The stabilizer 200 as illustrated has three plates/walls 240, 250 and 260 attached together and configured in a "Z" shape as seen in FIG. 2. The stabilizer 200 can also be formed from a single plate which is bent to form the "Z" shape seen in FIG. 2. The stabilizer 200 is preferably made of titanium. However, it can also be made of any suitable material including, but not limited to: polycarbonate, urethane and PEEK. The stabilizer 200 preferably has sharp edges 264 and

266 which are thin and strong enough to slice through vertebral bone when a sufficient force is applied to the anterior surface 270 of the stabilizer 200. The stabilizer translates along a line (L in FIG. 2) under the applied force to be pressed into the bone portion to which it is aligned for this and other embodiments herein. The sharp edges 264, 266 may be at both ends so that the stabilizer can be inserted with either end thereof in a leading direction. The stabilizer 200 can also have self-retaining clips 272 attached to it to help keep the stabilizer attached to the spacer after insertion, as will be discussed in further detail below.

[0132] FIG. 4 shows the spacer 100 operably implanted within a spine 402 from the anterior side of the spine. The spine 402 includes bone portions/vertebrae 410, 420. The spine 402 also includes a diseased/damaged disk 430 that has been partially removed and replaced with the spacer 100.

[0133] During operation, the diseased/damaged disk 430 is partially or completely removed and preferably replaced with the spacer 100 with the proximal surface 140 of said spacer 100 facing anteriorly. Stabilizers 200 are then lined up with the channels 155 of the spacer 100 and driven by translational movement into the vertebral bodies 410, 420 by applying sufficient force to the stabilizers 200. The stabilizers 200 are simultaneously driven into the vertebral bones 410, 420 and received into their respective channels 155. However, it is to be understood that in some embodiments, stabilizers 200 can be inserted into the vertebral bone before spacer 100 is inserted.

[0134] As mentioned previously, the stabilizer 200 can further include self-retaining clips 272 (see FIG. 2) to fixedly attach the stabilizers 200 to the spacer 100 after insertion. The self-retaining clips 272 of FIG. 2 are attached to the stabilizer 200 and curve outward. The self-retaining clips 272 are made of a resilient material which allows them to retract during insertion. Once the stabilizers are inserted, the self-retaining clips 272 expand and push against the inner wall of the channel 155, resisting withdrawal. The inner walls of the channels 155 can be made rough or with notches to further aid the self-retaining clips 272 in resisting withdrawal.

[0135] It will be appreciated that the stabilizer 200 can have a variety of shapes and that the spacer 100 can be configured with complementary channels shaped to receive the stabilizer 200.

[0136] FIGS. 5A and 5B illustrate an alternative embodiment of a stabilizer 500 suitable for use with a spacer (not shown), having channels shaped to receive the stabilizer 500. FIG. 5A is a top perspective view of the stabilizer and FIG. 5B is an end view of the stabilizer of FIG. 5A. As illustrated, the stabilizer 500 has a substantially sinusoidal configuration. While not illustrated, the spacer for use with the stabilizer 500 has a complementary channel having a substantially sinusoidal shape configured to receive the stabilizer 500. The complementary channel can be oriented perpendicular to the upper and lower surfaces of the spacer, or in any other orientation which would allow the stabilizer 500 to fixedly attach the spacer to an adjacent vertebral body.

[0137] FIGS. 6A-6J show various end views of alternative embodiments of differently shaped stabilizers, by way of example and not limitation. One of skill in the art will appreciate that any number of differently shaped stabilizers can also be used, though not identically disclosed herein, without departing from the spirit of the invention. Many of these embodiments include a length configured to span between the spacer and the vertebral body, but also a transverse compo-

ment (not shown in FIGS. 6A-6J) in both the spacer-engaging portion and the vertebral-body engaging portion configured to prevent separation between the spacer and vertebral body.

[0138] FIG. 6A illustrates an end view of a substantially “S” shaped stabilizer 601 suitable for use with a spacer (not shown), having channels shaped to receive the stabilizer 601. While not illustrated, the spacer for use with the stabilizer 601 has a complementary channel with a substantially “S” shape, configured to receive the stabilizer 601. The complementary channel can be oriented perpendicular to the upper and lower surfaces of the spacer, or in any other orientation which would allow the stabilizer 601 to fixedly attach the spacer to an adjacent vertebral body.

[0139] FIG. 6B illustrates an end view of a substantially double “Z” shaped stabilizer 602 configuration suitable for use with a spacer (not shown), having channels shaped to receive the stabilizer 602. While not illustrated, the spacer for use with the stabilizer 601 has a complementary channel having a substantially double “Z” shape, configured to receive the stabilizer 602. The complementary channel can be oriented perpendicular to the upper and lower surfaces of the spacer, or in any other orientation which would allow the stabilizer 602 to fixedly attach the spacer to an adjacent vertebral body.

[0140] FIGS. 6C-6J similarly illustrate end views of uniquely shaped stabilizers 603-610 configured for use with suitable spacers (not shown) having complementary channels shaped to receive each uniquely shaped stabilizer. The complementary channels can be oriented perpendicular to the upper and lower surfaces of the spacer, or in any other orientation which would allow the stabilizers to fixedly attach the spacers to an adjacent vertebral body.

[0141] FIG. 7 depicts a front end view of yet another embodiment of an interbody spacer 700. The spacer 700 has channels 755 configured to receive at least one stabilizer, such as the stabilizer 605 (see FIG. 6E). The spacer 700 has first and second surfaces, 760 and 770 respectively, configured to engage adjacent vertebral end plates. In this embodiment, the first and second surfaces 760 and 770 are substantially parallel. However, in other embodiments, the first and second surfaces can be angled relative to each other, so as to better support adjacent vertebral bodies in a more natural spinal alignment configuration. The spacer 700 of the present embodiment has two channels 755 for receiving stabilizers such as the stabilizer 605, although it is to be understood that in other embodiments, the spacer 700 can have only one channel or more than two channels.

[0142] The interbody spacer 700 can be provided with self-retaining clips 780 to help keep the stabilizers attached to the spacer 700 after insertion. The self-retaining clips 780 can be attached to the proximal surface 785 of spacer 700 and partially extend in front of the channels 755. Preferably, the self-retaining clips 780 have a first and a second position. In the first position, the clip 780 is retracted during insertion of the stabilizer. After the stabilizer is inserted, the clip 780 extends, assuming a second position. The self-retaining clips 780 can be made of a resilient material which allows them to bend inward during insertion of a stabilizer. Once the stabilizer is inserted into the spacer, the self-retaining clips 780 can “pop out” towards their original positions to impede withdrawal of the stabilizers.

[0143] FIG. 9 illustrates schematically another embodiment of an interbody spacer 900, similar to the spacers seen in FIGS. 8G and 8H depicting various “Novel VC Spinal Spacers”

for use in Anterior Lumbar Interbody Fusion (ALIF), which are commercially available from Alphatec Spine™, Inc. (See website at: <http://www.alphatecspine.com/products/interbody.asp>).

[0144] In preferred embodiments, the spacer 900 is used in spinal fusion surgeries, including ALIF procedures, though other implants and procedures are also contemplated.

[0145] The spacer 900, shown schematically in FIG. 9, includes first and second opposite surfaces, 920 and 930 respectively configured to engage superiorly and inferiorly the end plates of adjacent vertebrae. These surfaces 920 and 930 may have ridges, bumps or other protrusions to enhance engagement with the vertebral endplates as discussed above, and shown in FIGS. 8A-8M. As shown in FIG. 9, the first and second opposite surfaces, 920 and 930 may define openings 932 to allow for fusion through the openings. In the embodiment shown in FIG. 9, the first and second surfaces 920 and 930 are substantially parallel. However, in other embodiments, the first and second surfaces can be angled relative to each other, so as to better support adjacent vertebral bodies in a more natural spinal alignment configuration, as discussed previously.

[0146] The spacer 900 has a proximal face 934 and a distal face 936, the proximal face 934 corresponding to the end that engages a delivery tool, such as with grooves, indentations or a threaded opening 938, similar to that discussed above with reference to FIGS. 8A-8M. For an ALIF procedure, the proximal face 934 corresponds to the anterior face of the spacer and the distal face 936 corresponds to the posterior face of the spacer.

[0147] As illustrated in FIG. 9, the spacer 900 has two channels 955 for receiving suitable stabilizers (discussed in further detail below), although it is to be understood that in other embodiments the spacer can have only one channel and in yet other embodiments, the spacer can have any number of channels.

[0148] The channels 955 interface with the first and second surfaces 920 and 930 of the spacer 900, as well as with at least the proximal surface 934 of the spacer 900. The channels 955 shown in FIG. 9 extend through the body of the spacer 900, and interface with the distal surface 936 of the spacer 900. However, in other embodiments, the channels do not extend all the way through the spacer body to interface with the distal surface of the spacer and in other embodiments the channels 955 can interface with side surfaces 960 and 970. The channels 955 are preferably pre-cut into the spacer 900 before insertion into the vertebral space during surgery. Where the spacer 900 has openings 932 in the surfaces 920 and 930, the channels 955 may extend through solid portions of the spacer 900 between the openings 940 (such as through the intermediate bar 972 shown in FIG. 9), or they may be interrupted by the openings 932 so that the channels 955 are provided on opposite sides of the openings 932.

[0149] FIGS. 10 and 11 illustrate one embodiment of a stabilizer 1000 suitable for use with the spacer 900 of FIG. 9, where FIG. 10 is an end view of the stabilizer 1000 and FIG. 11 is a perspective view of the stabilizer 1000. The stabilizer 1000 is configured to be partially received within the channels 955 of the spacer 900, with a portion extending out of the channel 955 away from the surface 920 or 930 into the adjacent vertebral body. The stabilizer 1000 is preferably thin enough to slice through bone, yet strong enough to hold onto the bone and stabilize the spacer 900 after insertion. The stabilizer 1000, as illustrated, has two plates/walls 1050 and

1060 and a wall/retaining member **1070** attached together and configured in a “T” shape as seen in FIG. 10. The stabilizer **1000** is preferably made of metal but it can also be made of any suitable material including, but not limited to: Ti-6Al-4V, ELI, ASTM F 136, commercially pure titanium (for example, Ti-CP2, ASTM F 67, CPTi, etc.). The plates **1050** and **1060** of stabilizer **1000** preferably have sharp edges **1072** and **1074** which are thin and strong enough to slice through vertebral bone when a sufficient force is applied to the anterior surface **1076** of stabilizer **1000**. Stabilizer **1000** can also have self-retaining clips (not shown) attached to it to help keep the stabilizer **1000** attached to the spacer **900** after insertion, as discussed previously.

[0150] FIG. 12 is an end view of the spacer **900** of FIG. 9 operably implanted within a spine **1201** from the anterior side of the spine. The spacer **900** is inserted between two bone portions/vertebrae **1210** and **1220** and two stabilizers **1000**, according to FIGS. 10 and 11, are inserted into the channels **955** of the spacer **900** and into the adjacent vertebral bodies **1210** and **1220**.

[0151] During operation, the diseased/damaged disk (not shown) is partially or completely removed and preferably replaced with a spacer **900** with the proximal surface **934** of said spacer **900** facing anteriorly. Stabilizers **1000** are then lined up with the channels **955** of the spacer **900** and driven translationally into vertebral bodies **1210** and **1220** by applying sufficient force to the stabilizers **1000**. The stabilizers **1000** are simultaneously driven into the vertebral bones **1210** and **1220** and received into their respective channels **955**. However, it is to be understood that in some embodiments, stabilizers **1000** can be inserted into the vertebral bones **1210** and **1220** before spacer **900** is inserted. It is further conceivable, with this and other embodiments, that the stabilizers could be pre-joined to their respective spacer before the stabilizer is translated into the bone portions.

[0152] It should be understood that all of the particular structures described in each embodiment may be used in any other embodiment. That is, the invention contemplates that the different features in the embodiments disclosed herein may be interchanged.

[0153] As noted previously, it is contemplated that the invention can be practiced as part of any medical procedure involving the placement of a spacer between adjacent bone portions. This generic concept is shown schematically in FIG. 13, wherein a spacer **1300**, representing all spacer configurations disclosed herein, as well as others, is operatively joined to at least a first bone portion **1302**. It is conceivable that the spacer **1300** would be joined to only the first bone portion **1302**. However, more commonly, the invention would be practiced by using the spacer **1300** between the first bone portion **1302** and a second bone portion **1304**, which is shown to be optional by the depiction of the latter schematically in FIG. 13 in dotted lines. The stabilizer **1306**, as shown in FIG. 13, is intended to represent all stabilizer constructions disclosed herein, as well as others. The stabilizer **1306** operatively interacts between the spacer **1300** and either of the bone portions **1302**, **1304**.

[0154] With the system as shown in FIG. 13, the spacer **1300** is configured to be placed between the first and second bone portions **1302**, **1304**. The stabilizer **1306** is configured to be joined: a) to each of the first bone portion **1302** and spacer **1300**; and b) to at least one of the first bone portion **1302** and spacer **1300** by being translated relative to the at least one of the first bone portion **1302** and spacer **1300** along a first line.

[0155] As noted previously, the stabilizer **1306** preferably extends into its associated bone portion **1302**, **1304** over a majority of the dimension of that bone portion **1302**, **1304** along a corresponding first translation line L, as seen in FIG. 2 for the stabilizer **200**.

[0156] As seen in FIGS. 2 and 3, the stabilizer **200** has the aforementioned plates/walls **240**, **250**, **260**, with a first and second of the walls **250**, **260** having facing surfaces S1, S2, respectively. With the stabilizer operatively positioned, as seen in FIG. 4, a part P1 of the vertebra **420** and a part P2 of the spacer **100** are captive between the facing surfaces S1, S2 to stabilize the spacer and bone portion/member **420**.

[0157] Because each of the plates/walls **240**, **250**, **260** has a substantial width dimension transversely to the line L, the connection is stabilized in all critical dimensions. Preferably, the plates/walls **240**, **260** extend into the spacer **100** along a majority of the dimension of the spacer **100** along the line L. More preferably, the spacer walls **240**, **250**, **260** extend along substantially the entire dimension of the spacer **100** along the line L.

[0158] Each of the stabilizer configurations defined herein has surfaces that produce the above captive arrangement. By reason of the depicted configurations, these stabilizers also produce multidimensional reinforcement between the fused components.

[0159] As seen in FIG. 4, the spacer surface **120** abuts to an adjacent surface AS1 on the vertebra **410**, with the opposite spacer surface **130** abutting the adjacent surface AS2 on the vertebra **420**. It is contemplated that the stabilizers **200** extend through at least one of the surfaces **120**, AS1 and **130**, AS2 at locations where the surfaces abut. More preferably, each stabilizer extends continuously through each of the adjacent faces **120**, AS1 and **130**, AS2.

[0160] It is conceivable that a spacer could be devised having a U-shaped configuration, with spaced legs parallel to each other and the line L, such that the spacer does not penetrate any of the surfaces **120**, **130**, AS1, AS2. This spacer would be inserted similarly in a translational path.

[0161] As seen in FIG. 4, the surfaces **120**, **130**, AS1, AS2 are shown to be generally flat and parallel to each other. The translation line for the stabilizers **200** during assembly is substantially parallel to each of the surfaces **120**, **130**, AS1, AS2.

[0162] As also seen in FIG. 4, the inventive stabilizer **200** is constructed so that it extends only partially through the dimension of the spacer **100** between the surfaces **120**, **130**.

[0163] As further seen in FIG. 4, each of the components **410**, **420**, **100** has a peripheral surface, PS1, PS2, PS3. The stabilizers **200** can be constructed so that the stabilizers do not project from any of the exposed peripheral surfaces PS1, PS2, PS3. While preferred, this is not a requirement.

[0164] Additional variations of the inventive structure are shown in FIGS. 14-21.

[0165] In FIG. 14, a fenestrated form of stabilizer **1400** is depicted with a configuration corresponding to the stabilizer **610** in FIG. 6J. The stabilizer **1400** has flat walls **1402**, **1404** which combine to produce a “T” shape. A cylindrical wall **1406** is provided at the bottom of the “T”.

[0166] The wall **1402**, that is embedded in the bone, has discrete openings **1408** into which bone can grow to thereby further secure the connection between the stabilizer **1400** and bone.

[0167] In FIG. 15, a stabilizer **1500** is shown for use in conjunction with a spacer **1502** and bone portion **1504** to

cause facing surfaces **1506**, **1508** on the spacer **1502** and bone portion **1504** to be urged towards each other with a progressive camming action as the stabilizer **1500** is inserted.

[0168] The stabilizer **1500** has flat walls **1510**, **1512** that produce a “T” shape, at the bottom of which a cylindrical wall **1514** is provided. The wall **1514** resides within a reference plane RP. The wall **1514** has a central axis **1516** that is non-parallel to the reference plane RP. More specifically, the axis **1516** is oriented so that the space between the reference plane RP and axis **1516** increases between the trailing end **1518** and leading end **1520**.

[0169] The spacer **1502** has a channel **1523** to accept the wall **1514** and a part of the wall **1512**. The axis **1524** of the channel portion that accepts the cylindrical wall **1514** is substantially parallel to the spacer surface **1506**. As a result, as the leading end **1520** is translated into the channel **1523** and the wall **1510** cuts into the bone portion **1504**, the movement of the cylindrical wall **1514** into the channel **1523** produces a camming action that progressively urges the surfaces **1506**, **1508** against each other.

[0170] In FIG. 16, a stabilizer **1600** is shown in relationship to a spacer **1602** and bone portion **1604**, wherein a similar camming action is produced by essentially reversing the construction shown in FIG. 15. That is, the axis **1606** on the spacer **1602**, that corresponds to the axis **1524**, is inclined relative to the spacer surface **1608**, whereas the axis **1610** for the cylindrical wall **1612** is substantially parallel to a reference plane RP1 containing the flat wall **1616**.

[0171] Using the concepts disclosed in FIGS. 15 and 16, the components can be configured to produce the desired compressive force between a spacer and bone portion, as well as potentially producing such a force at both sides of the bone portion.

[0172] While the walls **1514**, **1612** are shown with a cylindrical shape, it is contemplated that the shape may be non-circular in cross-section so as to be keyed within the cooperating channel to further stabilize the connected spacer and bone portion.

[0173] The invention also contemplates that locking assemblies might be incorporated into the stabilizers and spacers to avoid inadvertent backing out or extension of the particular stabilizer at a fusion location. In FIG. 17, one form of locking assembly is shown at **1700**. A stabilizer **1702** has the same general construction as the stabilizer **1600** in FIG. 16, with the exception that there is an enlargement **1704** on the trailing end thereof. A cooperating spacer **1706** has a complementary channel **1708** including an enlarged receptacle **1710** that is complementary to the enlargement **1704**. The enlargement **1704** and receptacle **1710** define cooperating connecting parts on the locking assembly **1700**. With the stabilizer **1702** translated along the line L to a fully inserted position, the enlargement **1704** snap fits into the receptacle **1710** to produce a detent-type action.

[0174] In the depicted embodiment, the enlargement **1704** is countersunk so as to not project from the spacer **1706**. However, the parts could be configured so that there is a flush relationship or a projection of the enlargement **1704** from the spacer **1706**.

[0175] With this arrangement, the locking assembly **1700** maintains the stabilizer **1702** in its operative position shown in FIG. 17.

[0176] Another type of locking assembly is shown in two different forms in FIGS. 18-20. The locking assembly in FIGS. 19 and 20 consists of a reconfigurable body **1800** on a

stabilizer **1802**. The stabilizer **1802** is directed into a channel **1806** on a spacer **1808**. The channel **1806** has a flared region **1810** inset from a wall portion **1812**. The flared region **1810** defines an annular shoulder **1814** set inwardly from a surface **1815** on the spacer **1808**.

[0177] With the stabilizer **1802** translated into the channel **1806**, a bifurcated end **1820** of a cylindrical wall **1822** resides at the flared region **1810**. The bifurcation at the end **1820** produces diametrically opposite tabs **1830**, **1832** between which a threaded spreader element **1840** can be directed. The spreader element **1840** has an outer surface **1842** with a portion having a progressively increasing diameter. By threading the spreader element **1840** into the wall **1822**, the tabs **1830**, **1832** are reconfigured by bending radially outwardly to seat behind the annular shoulder **1814**, whereupon the stabilizer **1802** is blocked from being withdrawn. The spreader element **1840** thus changes the locking assembly from the assembly state, as shown in solid lines in FIGS. 19 and 20, to a locked state as shown in dotted lines in FIG. 20. The tabs **1830**, **1832** and flared region **1810** make up cooperating connecting parts on the locking assembly.

[0178] In FIG. 18, the locking assembly consists of corresponding tabs **1830'**, **1832'**, on a stabilizer **1802'**, that cooperate with a complementarily-shaped region **1810'** of a channel **1806'**. The tabs **1830'**, **1832'** may spring oppositely into the region **1810'** without requiring insertion of a separate spreader element.

[0179] As an alternative form of locking assembly, as shown in FIG. 21, a stabilizer **1900** is provided with a locking tab **1902**. The locking tab **1902** has a bore **1904** therethrough and is bent on site or pre-bent to be substantially orthogonal to the plane of a wall **1906** on the stabilizer **1900**. With this arrangement, the locking tab **1902** overlies a part of the exposed bone portion **1910** whereby a threaded fastener **1920** can be directed therethrough. The fastener **1920** is preferably a threaded component. A similar tab (not shown) might be provided to be securable to the cooperating spacer **1930** in like fashion.

[0180] Threads **1940** might be provided around the bore **1904**. The threads **1940** may be interrupted or placed at multiple points to allow for a controlled cross-threading of the head **1942** of the fastener **1920** as it is inserted. This allows the fastener **1920** to be inserted at any optimal angle.

[0181] In other variations, stabilizers, such as the stabilizer **1400**, may be treated by applying bone ingrowth coating, as on the wall **1402**. The coating may be in the form of beads, mesh, or hydroxyappetide. This promotes rapid ingrowth into the openings **1408**. This same concept may be used on all other stabilizers described herein.

[0182] FIGS. 22A-22D show a further variation of a spacer presented earlier. Like the spacer **900** illustrated in FIG. 9, the spacer/cage **2200** has a body **2290** with side surfaces **2260**, **2270**, channels **2255**, **2265**, proximal and distal faces **2240**, **2250**, respectively, first and second opposite surfaces **2210**, **2220**, an opening **2232** for graft or other bone substitute material, and protrusions in the form of teeth **2235**.

[0183] FIGS. 23A-23E show a further modified form of stabilizer **2300**. Like the stabilizers **1000**, **1400** illustrated in FIGS. 10, 11, & 14, the stabilizer **2300** has a wall/plate **2310**, a web/wall **2320**, and cylindrical wall/retaining member **2330** with a sharp leading edge **2340** to cut bone against which it is advanced. The stabilizer **2300** has self-retaining clips **2350** in the form of barbs/tabs, generally of the type illustrated at **272** in FIG. 2.

[0184] The spacer body 2290 has a height “h” sized to fit within a portion of the intervertebral disc space. The intervertebral space, as defined by the shape/footprint of the vertebral body endplates, is generally “D”-shaped and the implant spacer/cage 2200 preferably has an outer profile shape to fill substantially the entire disc space. Interbody implants may take streamlined profiles, as between anterior and posterior sides, to provide less invasive entry into the intervertebral space during surgery and to help accommodate to the surgical approach. Regardless of their configuration, it is desirable that the combined spacer and stabilizer have a “zero-profile”, meaning that no part of either component protrudes from the space between adjacent bone portions. Exemplary differing profiles are illustrated in FIGS. 8A-8M. For example, rectangular or banana-shaped profiles may be used since they are thinner in a width dimension, thereby requiring a smaller/less invasive path of entry into the intervertebral disc space. In one preferred form shown in FIG. 22A, an anterior wall portion 2275 of the implant, that is part of a continuous profile wall 2280 and defines the surface 2260, has a gentle convex arc similar to the anterior wall of the vertebral body and a predetermined width between the surfaces 2260 and 2270 to facilitate minimally invasive entry along an axis/line generally parallel to the lengths of the channels 2255 and 2265.

[0185] The outer profile wall 2280 defines one or more openings 2232, 2295 for packing bone graft or other bone substitutes to ultimately facilitate fusion between vertebral bodies. The opening 2232 is completely surrounded by the wall 2280 to hold the graft material within the body 2290. The wall 2280 may have openings partially or fully therethrough for packing graft. As seen in FIG. 22A, two graft apertures/openings 2295 are formed within the wall 2280 and can be utilized for adding additional graft or hydration to the graft within the opening 2232.

[0186] The proximal face 2240 of the wall 2280 of the spacer/cage 2200 incorporates features for the attachment of one or more auxiliary instruments utilized to install the spacer/cage 2200 within the intervertebral space. In this embodiment, instrument attachment structure is in the form of two bores 2215a, 2215b with at least one hole/bore 2215a threaded for attachment to a complementarily-threaded insertion facilitating instrument, identified schematically in FIG. 22A at 2205. The second hole 2215b is also shown to be threaded, though this is not required, and configured to engage a boss from the insertion instrument 2205 as a means to counter torque and therein limit rotation between the spacer/cage 2200 and insertion instrument 2205, to be described later. The instrument attachment portion structure could also be in other forms such as a boss, slot, hole, groove or other feature for an auxiliary instrument to attach. If both holes/bores 2215a, 2215b are threaded and usable individually to cooperate with the instrument 2205, the unused hole/bore 2215a, 2215b is available as a backup, as in the event one of the holes/bores becomes stripped.

[0187] The distal face 2250 of the body 2290 has a nose portion 2400 as seen most clearly in FIG. 22C, configured to ease entry into the intervertebral space by wedging between vertebral endplates during insertion. This nose portion 2400 preferably has a lead in angle taper at 2410, in combination with a radiused end 2420 defining a blunt arrow or bullet shape. As seen from the top view in FIG. 22D, the side surfaces 2260, 2270 may also have a taper or radius 2411 where they blend into the radiused end 2420 at the distal face

2250. This is helpful to wedge soft tissue to the sides of the nose portion 2400 during insertion.

[0188] The body 2290 also has a stabilizer attachment or anchor portion 2245 for securement of the stabilizer 2300 to the spacer/cage 2200. This anchor portion 2245 consists of one, and preferably two, of the aforementioned channels 2255, 2265 illustrated and otherwise known as keel tracks in this embodiment. The channels 2255, 2265 are at the site where the stabilizer 2300 attaches and is secured to the spacer body 2290. The channels 2255, 2265 are shown through the surfaces 2210 and 2220, but in some embodiments may be on other surfaces, such as the surfaces 2260 and 2270. The channels 2255, 2265 are preferably configured wherein one channel 2255 is adjacent one bone portion and the other channel 2265 is adjacent another between which the spacer/cage 2200 resides. The channels 2255, 2265 in this embodiment each is in the form of a T-shaped slot preferably extending along a linear path, although the path could be arced, when complemented by an arced stabilizer, or otherwise shaped. The T-shaped slot shown is configured to accept and contain a stabilizer, such as the stabilizer 2300 with a body 2390. The stabilizer body 2390 has one or more reconfigurable tabs/barbs 2350, and in this embodiment two such tabs/barbs 2350 generally of the type 1830, 1832 shown in FIGS. 19 and 20, and described in greater detail below.

[0189] At least one of the channels/keel tracks 2255, 2265 has a stabilizer stop portion 2276, here illustrated as a termination of the T-shaped channel 2255 which prevents the stabilizer 2300 from advancing beyond the spacer body 2290 and the implant spacer/cage 2200 from advancing out of the intervertebral space once the stabilizer 2300 is locked in a predetermined operative position within the vertebral body. With the stabilizer body 2390 abutted to the stop portion 2276, the stabilizer 2300 is consistently located in its optimal operative relationship to the spacer/cage 2200. The stabilizer anchor portion 2245 in this embodiment also has a stabilizer lock portion illustrated in FIG. 22B as an undercut region 2225 for receipt of the tabs/barbs 2350 on the stabilizer 2300.

[0190] In FIG. 22B, both of the opposite surfaces 2210, 2220 of the body 2290, on the superior and inferior sides thereof, have channels 2255, 2265 respectively formed therethrough with each shown as a T-shaped slot. The body 2290 of the spacer/cage 2200 may have one or more marker housings 2285 shown here in the form of holes or other recess for the placement of tantalum markers M. The markers M assist placement of the implant through imaging in the predetermined intervertebral position.

[0191] As shown in FIGS. 22A and 22C, the first and second opposite surfaces 2210, 2220 of the implant body 2290 ride directly against bone. One or both surfaces 2210, 2220, as shown, may have one or more of the teeth 2235 or other protrusions to assist securement of the spacer/cage 2200 in its predetermined operative position between the vertebral body bone portions BP1, BP2, as seen in FIG. 24A. The teeth 2235 preferably each has a peak 2236 which may be in the form of a point, or broader surface such as a line, preferably extending generally transverse to the entry line/axis. Each tooth 2235 has an entry face 2237 that may be sloped to assist moving the implant body 2290 into the intervertebral space, and a trailing face 2238 that is more steeply sloped to engage a bone portion to prevent the implant body 2290 from backing out of the implant space. The teeth 2235 are sized deep enough to dig into bone yet shallow enough to avoid substantial loss of

intervertebral space following implant insertion once there is subsidence of the teeth or other protrusions 2235.

[0192] The opposite surfaces 2210, 2220 are preferably optimized to have enough area to adequately support and distribute the forces between the vertebral body endplates while having adequate sized openings 2232 for a strong fusion. In turn, the wall 2280 of the body 2290 is thick enough such that it will not buckle under the endplate forces, dependent on the material of construction. The distance *h*, between the surfaces 2210, 2220, is generally equal to the distance between vertebral body endplates when separated by a healthy intervertebral disc. These surfaces could be generally flat; however, they are preferably contoured to match the contour of the facing vertebral endplate, which is typically slightly convex. An example of the contour can be seen in FIG. 22C with the height bulged slightly near the middle of the spacer/cage 2200. Similarly, the opposite surface portions 2210, 2220 may be angled in relation to each other to accommodate to the intervertebral space. This space is commonly angled from anterior to posterior. As an example, the embodiment in FIG. 22C is angled 6°, as reflected by a slightly greater height on the anterior portion of the implant and sloping to a slightly shorter height on the posterior portion of the implant. This corresponds to the normal angulation in the lumbar spine.

[0193] The stabilizer 2300 functions to: secure the body 2290 portion in a predetermined operative position relative to the adjacent bone portions; assist against back out and over travel of the spacer/cage 2200 from this position; and help positively hold surrounding bone close to the spacer 2200, thereby facilitating a successful fusion. The wall/retaining member 2330 on the stabilizer 2300, in the preferred embodiment depicted, has a cylindrical shape. The stabilizer 2300 has a reconfigurable body 2390, generally of the type illustrated in FIGS. 19 and 20, but could have a multitude of other configurations also described elsewhere. The stabilizer 2300 may be integrated with the spacer/cage body 2290, but it is preferred that it be a separate component as shown clearly in FIGS. 23A and 238. The stabilizer 2300 has a spacer anchor 2370 that resides within the stabilizer anchoring portion 2245 on the spacer/cage 2200 with the spacer/cage 220 and stabilizer 2300 operatively connected.

[0194] The base wall 2310 is flat and configured to be directed into a complementarily-shaped portion of either of the channels 2255, 2265 on the body 2290. In this case, the base wall 2310 and the flat web wall 2320 form a “T”-shaped portion to slide in and reside in one of the T-shaped channels 2255, 2265. The cooperating “T” shapes are such that the spacer anchor 2370 can be guided consistently within the channels 2255, 2265 along the assembly line/axis without excessive resistance but will be closely enough matched to be stabilized in multiple dimensions relative to the spacer/cage 2200 without appreciable wobble. The lower region of the web wall 2320 is thickened where it engages the spacer/cage 2200. The exemplary channel 2255 is bounded by a surface 2266.

[0195] The complementary shapes of the channels 2255, 2265 and spacer anchor 2370 may take many other forms besides a “T” shape. For example, the base wall 2310 could have a triangular, elliptical, or round profile. A leading nose 2311 on the base wall 2310 serves to lead the base wall 2310 into a channel 2255, 2265 of the stabilizer anchor 2245. Similar to the spacer nose 2400, it is preferred that the nose 2311 is tapered and radiused to ease entry. As seen in FIG.

23C, the base wall nose 2311 extends slightly ahead of a reconfigurable nose 2361 on the body 2390 such that the base wall 2310 can begin to seat in one of the channels 2255, 2265 before the reconfigurable nose 2361 is situated to seat in the body of the vertebrae, thereby easing insertion complications.

[0196] Any portion of the spacer anchor 2370, but preferably the base wall 2310, includes a self-retaining portion. The base wall 2310 has a generally flat wall surface 2380 that is abutable to the spacer/cage surface 2266 to prevent pullout of the base wall 2310 from the channel 2255 in a direction transversely to the channel length. A preferred configuration of the self-retaining portion is shown in FIG. 23B in the form of the aforementioned tab/barb 2350. One or more of the tabs/barbs 2350 may be used. These tabs/barbs 2350, shown as two in number, are each configured to engage the stabilizer lock portion, shown in the form of a like number undercut regions 2225. The tabs/barbs 2350 are formed on the stabilizer base wall 2310 and extend slightly below the base wall 2310. As the base wall 2310 is inserted into exemplary channel 2255, resilient arms 2351 on each tab/barb 2350 serially engage an edge 2239 where a face 2241 bounding the channel 2255 meets the proximal face 2240 and deflects up then re-seats itself under a restoring force when it aligns over an undercut region 2225 on the stabilizer interlock. This progression is illustrated in FIGS. 23B through 23E.

[0197] A portion of the stabilizer body 2390 is cut away in the illustrations for enhanced visualization. FIG. 23B illustrates the leading base wall nose 2311 approaching one of the channels 2255 with the spacer 2200 and stabilizer in a pre-assembly relationship. FIG. 23C illustrates the stabilizer 2300 partially seated into the spacer/cage 2200 but before the tabs/barbs 2350 are engaged. FIG. 23D illustrates the stabilizer 2300 further translated into the spacer/cage 2200. The underside surface of each self-retaining tab/barb 235 abuts the bottom surface 2241 of the channel 2255 and is guided therealong until the tabs/barbs 2350 align over their respective undercut region 2225 whereupon a restoring force in the deflector arms 2351 drives them into the undercut regions 2225. A curved edge/blocking surface 2227 bounding each undercut region 2225 confronts the trailing edge/blocking surface of one of the tabs/barbs 2350 to block the stabilizer 2300 from backing out. FIG. 23E illustrates the stabilizer 2300 fully translated into the channel 2255 and the spacer 2200 and stabilizer in assembled relationship. Stop 2275 prevents further translation of the stabilizer 2300 moving in its assembly direction. The stabilizer 2300 is thus fully locked consistently in a preselected, optimal operative position relative to the spacer/cage 2200.

[0198] The tabs/barbs 2350 may each have a sloped leading surface 2353 to assist deflection of the tabs/barbs 2350 upon entry and a steeper surface 2354 on the trailing end of the tabs/barbs 2350 to confront the edges 2227 bounding the undercut regions and prevent backout. The transition between the leading surfaces 2353 and trailing surfaces 2354 may be rounded to prevent hang-ups. The spaces above the tabs/barbs 2350 are open to form relief pockets 2352 to allow for adequate deflection of the tabs/barbs 2350 when inserting into the channel, as described previously. The barb arms 2351 are long enough to assure adequate deflection of the barbs 2350 while minimizing plastic deformation. The backout stop edges 2227 are each in the form of a steep wall located at the trailing end of the undercut regions 2225, one of which is adjacent the proximal face 2240 with the spacer 2200 and stabilizer 2300 in operative relationship. The stop edges 2227

secure the stabilizer **2300** captively in conjunction with the stop portion **2276** and help prevent the tabs/barbs **2350** from slipping out of the undercut regions **2225** as might allow unintended release of the stabilizer **2300** from the spacer **2200**.

[0199] With this arrangement, the stabilizer **2300** can be translated in a first direction in a first path relative to the spacer/cage **2200** and thereby snap-fit consistently into the same operative relationship therewith. The trailing surface **2354** and edges **2227** function as oppositely facing/blocking surfaces that confront each other to prevent separation of the operatively joined stabilizer **2300** and spacer/cage **2200** with the spacer/cage **2200** and stabilizer **2300** in operative relationship.

[0200] One preferred interface between the flat base wall **2310** and the channels **2255**, **2265** is the depicted “T”-shaped configuration. Although clearly other shaped channel interfaces can be used, such as triangular, this “T”-shaped interface creates good stability between the stabilizer **2300** and the spacer/cage **2200** and in turn results in greater stability of the adjacent bone portions. The “T”-shaped profile has beneficial strength to thickness ratio; that is, the base wall **2310** is thin yet strong, therein maximizing the material thickness of the spacer/cage **2200** available to secure the stabilizer **2300** thereto. This permits narrower implants to be created for use in patients having small stature or narrow disc spaces. It is preferred that the interface gap between the surfaces of the base wall **2310** and the walls bounding the channels **2255**, **2265** is large enough to allow insertion of the stabilizer **2300** into the track without struggle, yet small enough to minimize motion between the two components, thereby adequately stabilizing the surrounding bone.

[0201] Depending on where the implant is used in the skeleton, or elsewhere as is also contemplated, the positioning of the stabilizer **2300** on the spacer/cage **2200** may affect performance and/or ease of insertion. Therefore the stabilizer **2300** may be positioned midline or asymmetrically or at any number of angles with respect to the body portion of the implant. For example, in the illustrated and preferred embodiment of FIG. 22B, preferably utilized for a lateral surgical approach, the stabilizer **2300** is positioned to the posterior side of the implant as illustrated by the position of the stabilizer anchor channels **2255**, **2265**. When appropriately placed in the intervertebral space, this position locks the stabilizer **2300** to the endplate of the vertebrae near the center of axis of rotation between the vertebral bodies. This placement is also particularly effective at resisting the vertebral endplate from lifting away from the opposite surface portions **2210**, **2220** of the implant body **2290**. In this embodiment, the asymmetrical positioning of the stabilizer **2300** also makes possible the use of a single large opening **2232** for the bone graft instead of two smaller ones. In most cases, the channels/keel tracks **2255**, **2265** will be generally collinear with the path of entry of the surgical approach.

[0202] The web wall **2320** is typically in the form of a thin wall, preferably about 1 mm or less, with a sharp leading edge **2340** to slice through bone as the stabilizer is advanced in its assembly direction and path, and has a profile narrower than the diameter of the cylindrical wall **2330** so the cylindrical wall **2330** is captive and cannot be pulled through the bone space created by the web wall **2320**, thereby securing the bone tightly to the opposite surfaces **2210**, **2220** of spacer/cage **2200**. The web wall **2320** spans along a majority of the length of the stabilizer **2300** between the cylindrical wall

2330 and flat base wall **2310**. It is preferred that the cylindrical wall **2330**, the web wall **2320**, and the base wall **2310** all extend fully to the stabilizer’s proximal face **2321**, that is substantially flat and resides in a plane generally orthogonal to the length of the stabilizer **2300**. The web wall **2320** is shown as the shortest of the three walls. This wall length difference facilitates insertion since the sharp edge **2340** will not encounter the wall of the vertebral body until after the reconfigurable nose **2361** and the base wall nose **2311** are at least partially inserted into the vertebral bone and channel **2255**, **2265**, respectively.

[0203] This web edge **2340** is sharpened to cut through bone during insertion. This sharpened edge **2340** may be vertical or sloped forward or back to facilitate the cutting action. In the preferred embodiment, the web edge **2340** is straight, but may also be curved or serrated. It is preferred that the web wall **2320** be continuous, but it may include apertures for eventual bone ingrowth. However, these should be limited so as to not substantially weaken the web wall **2320**. A continuous web will also ease future removal, if necessary, since bone cannot grow through the web openings. The web wall **2320** in FIG. 23A rises vertically from the flat wall track **2310**; however, this web could rise at an angle or in a curved path if so desired, as did those in earlier embodiments, such as that in FIG. 2.

[0204] The cylindrical wall **2330** in this preferred embodiment is a portion of the stabilizer **2300** that is configured with a surface **2303** that faces the base wall surface **2380**, to prevent the stabilizer from being pulled through bone as the cooperating bone portion attempts to pull away from the spacer/cage **2200** during normal movements of the patient. For purposes of the description and claims herein, the surfaces **2303**, **2380** are considered to be “facing” over the extent to which they are cooperatively capable of exerting a captive force on components therebetween. Essentially, the convex surface **2303** faces the base wall surface **2380** at all locations where the surface **2303** faces the plane within which the surface **2380** resides. The cylindrical shape of the wall **2330** affords a substantial bone contact area and thus improves overall stability without occupying a detrimentally large bone volume. The surface **2380** does not have to be formed as part of a continuous cylindrical surface as depicted, but is preferably convex where it faces the base wall surface **2380**. The convex portion preferably has a radius at or adjacent the lengthwise central axis shown for the cylindrical wall **2330**. The cylindrical wall **2330** may alternatively be an enlarged portion of the implant such as an elongated bulb or cylinder and is configured to prevent pullout from the vertebrae like the “T” shaped walls of the stabilizer spacer anchor **2370** prevent pullout from the channels **2255**, **2265**. The cylindrical shape of the cylindrical wall **2330** is well suited to occupy the space created by a drilled hole in the body of the vertebrae. This is advantageous since drills are one of the tools of choice for orthopedic surgeons since they perform well in narrow spaces, are easy to control, and can be used to form bores quickly. The cylindrical bore produced by drilling also is desirable from the standpoint of avoiding crack propagation. The continuously curved surface produced by boring does not have sharp corners or intersections at which there may be stress concentration.

[0205] Of course, other than a cylindrical shape for the wall/retaining member **2330** is contemplated. Other shapes, derivable by those skilled in the art, may be utilized to prevent the wall/retaining member from pulling through the bone. For

example, a “T”-shaped component could be utilized and has a more compact shape. Further, a convex surface may be formed without a full cylindrical shape.

[0206] The stabilizer cylindrical wall 2330 preferably has a reduced lead-in portion to ease insertion of the stabilizer 2200 into the bone. This is illustrated in FIGS. 23A and 23B in the form of a bullet tip-shaped nose 2361 with a tapered surface portion angled between a leading end and the surface 2303. As the stabilizer 2300 is advanced in its assembly path in the assembly direction, the tapered surface portion bears against the bone portion into which it is directed and progressively wedges that bone portion towards the spacer 2200. The nose 2361 is part of another reconfigurable body portion 2360. The reconfigurable body portion 2361 prevents backout of the stabilizer 2300 from the bone portion as well as preventing movement of the joined stabilizer and spacer relative to the bone portions in the assembly/advancing direction beyond the optimally identified location.

[0207] The reconfigurable body portion/nose 2361 is in the form of an expandable bulb 2362 at the leading end of the stabilizer cylindrical wall 2330. The reconfigurable body portion 2361 can take other forms such as a series of self-retaining clips or barbs deflected out into the bone. As illustrated in FIG. 23E and also in a similar arrangement in FIG. 19, the expandable bulb 2362 has one or more deflection gaps 2363 that bifurcate the reconfigurable nose 2361 into two or more parts. The deflection gap 2363 terminates at a relief bore 2364. The relief bore 2364 is preferably circular to minimize stress, thereby preventing material fracture. The material between the outer surface of the cylindrical wall and the relief bore defines hinged deflection walls 2365 that function as live hinge portions. The deflection walls 2365 are the portions of the bulb 2362 that undergo deformation, therein allowing separate repositionable body tabs 2366 to deflect about the hinge portion out to a diameter greater than that of the cylindrical wall 2330 and into bone, thereby retaining implant position. In the preferred embodiment, the two tabs 2366 expand to a diameter approximately 30% greater than the cylindrical wall diameter.

[0208] FIG. 24A is an illustration of an implanted spacer-stabilizer assembly 2401 with the tabs 2366 in the expanded and locked positions. The stabilizer wall 2330 in FIG. 24A is in a second position to which it has been moved, from a first position prior to entry into the bone portion BP1, wherein the stabilizer wall is aligned to initially enter the bone portion BP1. The spacer/cage 2200 is secured in the intervertebral space between the vertebral bodies 2410 (BP1), 2420 (BP2), with the spacer/cage 2200 and stabilizer in operative relationship with each other and the bone portions/vertebral bodies 2410, 2420. In this state, parts of each of the bone portion BP1 and the spacer 2200 are captive between the facing surfaces 2303, 2380. A portion of the vertebral body is cut away to illustrate the position of the stabilizers 2300 in the bone.

[0209] This stabilizer cylindrical wall 2330 has a central bore 2331 (FIG. 23A) terminating at, and contiguous with, the relief bore 2364. The bore 2331 has a central axis A. A portion of this bore, preferably at the trailing end, has threads 2332 or alternative connection mechanism, such as a bayonet connection, to securely contain a spreader 2421 (FIG. 24B) within the central bore 2331. The spreader 2421 has a diameter to occupy the central bore 2331 so that it will be guided in sliding movement therewithin, along the axis A. At the trailing end of the spreader 2421 are threads 2425, or other connection mechanism, to cooperate with the threads/con-

nection mechanism 2332, wherein the spreader 2421 is pushed into and then advanced by threaded rotation into the bore 2331, as seen in the transition between FIGS. 25A and 25B. As an outer surface of a tapered nose 2422 at the leading end of the spreader 2421 abuts the internal surface of the tabs 2366 of the reconfigurable stabilizer 2300, as seen in FIG. 25B, further advancement of the spreader 2421 causes the reconfigurable body tabs 2366 to deflect, with the upper tab 2366 in FIG. 25B deflected outwardly into the surrounding bone, thereby securing the stabilizer 2300 in place. The tabs 2366 are consistently fully deflected when a shoulder stop 2426 abuts the stabilizer proximal face 2321 and the internal surfaces of the tabs 2366 rest on a shaft face 2423.

[0210] Located at the proximal/trailing end of the spreader 2421 is a drive head 2429 which in this embodiment is a drive pocket 2427 with a regular array of drive faces 2424 thereon. The pocket 2427 is configured to receive and intermesh with drive faces 2434 on a drive head 2433 of a spreader driver 2430 (FIGS. 24C and 24D) such that turning of the spreader driver 2430 through a hand-graspable driver handle 2431 will advance spreader 2421 into the stabilizer 2300 for locking. The leading end of the drive head 2433 may be configured for eased insertion into the drive pocket 2427 by using a taper 2432, radius, or other means and may also have a shoulder 2435 to block insertion consistently at a preferred depth.

[0211] To prevent unintended separation of the spreader driver 2430 from the spreader 2421, the drive head 2433 may incorporate an anti-separation feature. For example, in this embodiment the drive head 2433 may be bifurcated one or more times to create repositionable arms 2437 separated by one or more deflection gaps 2436. It is preferred that the arms 2437 elastically spring out to create an outside diameter of drive head 2433 that is slightly larger than that of the drive pocket 2427 so that, when inserted, a frictional fit of the drive head 2433 within the drive pocket 2427 is created with the arms 2437 wedged towards each other, wherein the spreader 2421 is not prone to unintentionally falling off yet is easily released when needed by the surgeon by intentional retraction of the spreader driver 2430.

[0212] Different forms of instruments usable to install spacer/stabilizer assemblies into the affected intervertebral spaces are described below.

[0213] One embodiment of a spacer/cage inserter tool is shown at 2600 in FIG. 26A. The tool 2600 is attached to the spacer body 2290 at an instrument attachment portion 2208 of the implant spacer/cage 2200. The inserter tool 2600 has a connection tip portion 2640 at the distal end of a guide bar body 2630 which, in this embodiment, is in the form of a threaded prong 2632 and a non-threaded prong 2631 for engagement in the threaded attachment holes 2215a, 2215b in the implant body 2290. The non-threaded prong 2631 resides in the one of the instrument attachment holes 2215a, 2215b of the implant spacer/cage 2200 that may be unthreaded. As noted above, the holes/bore 2215a, 2215b are both shown to be threaded, for reasons stated. However, one may be unthreaded. The threaded prong 2632 threads into the other, threaded hole 2215a, 2215b and holds the implant spacer/cage 2200 tight to an inserter face 2633. Together, both prongs 2631, 2632 serve to maintain consistent alignment of the spacer inserter instrument 2600 with the implant body 2290 thereby controlling the implant spacer 2000 during insertion. The connection tip 2640 portion may take other forms such as a bayonet connection or clamping arms. The

instrument attachment portion 2208 is configured accordingly with a complementary structure.

[0214] The guide bar body 2630 has a handle portion 2620 for user control over the inserter tool 2600. This handle 2620 has a graspable length that is preferably oriented to be angled, in one form on the order of 90°, to the central axis of the body 2630. The guide bar body 2630 houses a locking shaft 2614 illustrated in FIG. 26B. A threading spool 2611 is used to turn the locking shaft 2614, which terminates at the threaded prong 2632. As the threading spool 2611 is hand rotated, the threaded prong 2632 seats into one of the threaded attachment holes 2215a, 2215b on the implant, therein securing the implant spacer/cage 2200 to the inserter tool 2600.

[0215] The surgeon may then grasp the handle 2620 and guide bar body 2630 to control insertion of the spacer/cage 2200 into the intervertebral space. The nose 2400 of the implant spacer/cage 2200 is guided into a predetermined position between the vertebral endplates. The surgeon may choose to tap an impact fitting 2610 with a hammer to assist driving the implant spacer/cage 2200 into the intervertebral space. This impact force is transmitted from a transmission face 2613 to the adjacent face of the guide bar body 2630 then through inserter face 2633 to the spacer proximal face 2240.

[0216] The guide bar body 2630 may have one or more apertures 2634 to facilitate viewing and/or cleaning. The length of the guide bar body 2630 is preferred to extend long enough that the handle 2620 can be grasped a comfortable distance outside of the patient's skin. The distal portions of the inserter tool 2600 are sized to pass through the internal channel formed by a tissue retractor.

[0217] The guide bar body 2630 may also cooperate with an accessory guide holder 2650, shown in FIGS. 26C and 26D, secured on or integrated into the outer surface of the body 2630 to hold and guide accessories/tools such as drill bits and drivers used in conjunction with the inserter 2600. The guide holder 2650 may have one or more accessory retainer portions 2660, with each of the two shown in the form of a spring-biased locking arm 2661. Each locking arm 2661 may have a resilient body integral with a main frame 2659 on the guide holder 2650 that springs toward a locking face 2663. This version is not shown in the drawings. FIGS. 26C and 26D illustrate, as a preferred alternative, a rigid locking arm 2661 movable about a pivot pin 2665. In a pivot gap 2666, a space is provided for a compression spring, or other biasing component 2662, to bias the locking arm 2661 in the direction of the arrow A to reposition the locking face 2663 thereon.

[0218] The accessory guide holder 2650 has a proximal face 2668 and a distal face 2667. Situated, preferably on at least the proximal face 2668, is an accessory positioner 2664 shown here in the form of a recess/aperture. In this embodiment, multiple, additional positioning recesses 2669 are provided. Some of the positioning recesses 2669 are shown as full, or blind, bores located different distances from the central axis of the guide bar aperture 2664 to reflect positioning required by accessories to be attached.

[0219] Illustrated in FIGS. 27A-27G are various exemplary instruments/components including a drill guide-drill assembly 2700, as shown in FIG. 27H. In one preferred form, the drill guide 2700 is interconnected with the spacer inserter tool 2600 to create an interdependent assembly that will improve stability of the drill guide 2700 and accuracy in placement of the spacer/cage 2200. This combined drill guide-spacer inserter assembly is shown at 2790 in FIG. 27G. It is possible, although less preferred, that the spacer inserter tool 2600 and

the drill guide-drill assembly 2700 are not interconnected. In this configuration, the drill guide 2700 may have its own handle 2711 depending from a proximal end. FIG. 27H illustrates the drill guide-drill assembly 2700 without the spacer insert tool 2600.

[0220] A preferred embodiment of the drill guide 2700 is illustrated in FIGS. 27A-27C. A drill guide body 2705 spans between a drill guide tip 2703 and a drill guide shoulder 2702. The drill guide body 2705 has an outer drill guide wall 2706, which in this case defines a drill guide cylinder 2701 to receive and guide a drill 2720 as shown in FIG. 27D. Although the wall 2706 is illustrated as a continuous cylinder, the wall 2706 may be discontinuous. For example, the wall 2706 may be in the form of a plurality of tabs extending from the drill guide body 2705 yet still functioning to contain and guide the drill 2720. Preferably at the proximal end of the drill guide body 2705, although it could be positioned elsewhere, the drill guide shoulder 2702 is provided. This shoulder 2702 interfaces with a drill guide stop 2722 on the drill 2720 to stop penetration of the drill 2720 into the bone at a predetermined depth. Also, preferably at the proximal end of the drill guide body 2705 is a positioner 2707 shaped to complement the accessory positioner 2664 on the accessory guide holder 2650. The positioner 2707 in this embodiment is in the form of a positioning boss 2708 configured to fit in one of the positioning recesses 2669.

[0221] The distally located tip 2703, seen clearly in FIGS. 27A and 27C, is configured in profile and size to complement the spacer's stabilizer anchor 2245, in this case to be slid into one of the spacer channels 2255, 2265 with which it has a complementary shape. The tip 2703 has a "T"-shaped configuration much like the stabilizer's spacer anchor 2370 in FIG. 23A. Similarly, the drill guide tip 2703 has a flat track or base wall 2712, a web wall 2710, and a base nose 2709. The base nose 2709 is tapered and radiused much like the stabilizer nose 2311 to simplify insertion into one of the channels 2255, 2265. The web wall 2710 extends upright from the base wall 2712 and is integrated into, or otherwise attached to, the drill guide body 2705. The tip 2703 also has a drill guide stop 2704, here in the form of a ridge extending out from the web wall 2710, to limit overinsertion once the stop 2704 abuts the proximal face 2240.

[0222] In a preferred embodiment, as shown most clearly in FIG. 27D, the drill 2720 has an elongate body 2729 with several features thereon. The proximal end of the drill 2720 has a drive shaft 2728 with drive faces 2723 thereon defining a polygonal outer drive surface. The drive faces 2723 are configured to be directed into a complementary shaped receptacle on the handle 2711. Alternatively, the drive shaft could be configured in the shape of a handle. The drill stop 2722 is configured in this case to abut the drill guide shoulder 2702 when the drill 2720 has reached its predetermined depth. The body 2729 may also include one or more radially enlarged, cylindrical alignment faces. This embodiment has a proximal alignment face 2726 and a distal alignment face 2727. When the drill body 2729 is situated within the drill guide wall 2706, these alignment faces 2726, 2727 are sized to have a diameter slightly less than the inner diameter of the drill guide cylinder 2701 to maintain alignment and minimize wobble of the drill 2720 during use. A base region 2725 is a recessed area in the body which may be configured to separate the alignment faces 2726, 2727 and for collection of bone chips as the drill 2720 engages with and removes bone. At the distal end of the drill 2720 is a cutting tip 2721 which is preferably tapered

back to engage the bone from a starting point. Cutting flutes 2724 extend back helically from the tip 2721 to carry bone chips away from the cutting tip 2721. The flutes 2724 and tip 2721 have sharp cutting faces 2730 on edges thereon to ease cutting through bone.

[0223] FIG. 27E is a close-up view of the proximal end of the drill guide-spacer inserter assembly 2790 of FIG. 27G. As the drill guide tip 2703 is inserted and translated into one of the channels 2255, 2265, the stop 2707 of the drill guide 2700 will approach the accessory positioner 2664. For this embodiment, the leading end of the positioning boss 2708 will align with a predetermined positioning recess 2669 and eventually be moved therein. As the leading end of the drill guide shoulder 2702 contacts the sloped entry face 2671 of the locking arm 2661, the locking arm 2661 will be cammed back until the trailing face of the drill guide shoulder 2702 passes and then is captured by the locking face 2663 once the locking arm 2661 springs back into position. In this state, the drill guide tip 2703 is fully seated in a channel 2255, 2265 and the drill guide stop 2704 abuts the proximal face 2240 of the spacer/cage 2200. The drill guide 2700 is thus fully docked to the spacer inserter tool 2600.

[0224] The surgical technique begins by preparing the patient using standard pre-op procedures. The patient is positioned on the operating room table consistent with the surgical approach required to gain disc space access. For example, the spacer illustrated in FIG. 9 is adapted best for an anterior surgical approach wherein the patient would be positioned supine on the operating table for an ALIF procedure. A surgical technique for a lateral approach is described below, as the spacer-stabilizer assembly of FIG. 24A is well suited to be inserted laterally. Clearly, the surgical technique can be easily adapted for other approaches.

[0225] For the lateral approach, the patient is typically positioned sidelying on the contralateral side of the incision site. EMG monitoring may be useful during surgery to help the surgeon steer clear of nerves near the surgical path.

[0226] Incisions from the lateral side, to open access to the surgical site, are made. Tissue dilators and/or retractor systems may be used to access the affected disc space along with access lighting. Using instruments such as shavers, curettes, and rongeurs, the diseased disc material is removed and the endplates are prepared and roughened to expose bleeding bone. Disc space sizing instruments, such as trial spacers and/or imaging, may be used to correctly size the spacer/cage 2200 and stabilizers 2300 required for the patient. The spacers and stabilizers may be provided in one or more surgical kits in a variety of sizes to suit the patient's anatomy along with instruments described above. This sizing may include not only measuring the gap between endplates, but also angles between the endplates, and the overall footprint size of the endplates.

[0227] The dimensions of the spacers 2200 of this embodiment will generally range from 7 mm to 17 mm in height (h), between 35 mm and 65 mm in length (L), and 11 mm to 21 mm in width (W). The angle between the superior and inferior endplate facing surfaces of the spacer generally ranges from 0-12 degrees.

[0228] The selected spacer is chosen from the surgical kit and just before or after attachment to the spacer inserter tool 2600 (as previously described), the spacer opening 2232 may be packed with a chosen graft material. The inserter tool 2600 with the selected spacer attached is then guided through the incision, down the corridor created by the retractor, until it has

reached its predetermined position in the intervertebral space. The placement of the implant may be checked by imaging and readjusted. Markers placed in the marker housings 2285 will show on imaging therein, assisting the surgeon in properly positioning the spacer. Unless preassembled, the tip 2703 of the drill guide 2700 is then guided along the guide bar body 2630 of the spacer inserter tool 2600 and directed into one of the channels/tracks 2255, 2265 of the spacer/cage 2200. The drill guide 2700 is translated until the drill guide 2700 abuts against the spacer/cage 2200 and/or the drill guide shoulder 2702 is captured under the locking face 2663. The drill guide tip 2703 is preferably configured in a "T" shape sized to easily slide into the spacer's channel 2255, 2265 with minimal play.

[0229] A drill 2720 of predetermined diameter is inserted into the cylinder 2701 of the drill guide 2700. The surgeon, utilizing hand force or power on the drive faces 2723, creates a bore/channel into the wall of the vertebrae by advancing the drill 2720 into the drill guide cylinder 2701 and vertebral body until the drill stop 2722 on the drill 2720 abuts the drill guide shoulder 2702, indicating that the full predetermined depth of the drill has been reached. The drill 2720 and guide 2700 are then removed. Locking the drill guide 2700 to the channel/keel track 2255, 2265 assures precise control over the starter hole position and angulation therein, assuring easy insertion of the stabilizer cylindrical wall 2330 later.

[0230] The stabilizer 2300 is now attached to a stabilizer inserter 2800, illustrated in FIGS. 28A and 28B. The stabilizer inserter 2800 has an elongate tube or shaft body 2801 with an insertion tip 2802 at a leading end. The insertion tip 2802 has a reduced diameter leading prong 2803 sized to occupy the central bore 2331 of the stabilizer cylindrical wall 2330. The prong 2803 assists to control the stabilizer 2300 during insertion. Stepped back from the prong 2803 is a threaded section 2804 of the insert 2800 configured to engage the internal threads 2332 of the stabilizer bore 2331. A stop 2805 abuts the proximal face 2321 of the stabilizer 2300 when the inserter 2800 is fully advanced and seated in the stabilizer 2300. The trailing end of the stabilizer inserter 2800 has an impact surface 2807 for tapping the stabilizer 2300 into position. A graspable handle 2806, in a preferred embodiment, has an enlarged tip 2809 upon which the surface 2807 is defined and which will contact the impact face 2612 of the spacer/cage inserter tool when the stabilizer is fully seated thereby preventing over penetration of the stabilizer 2300.

[0231] Utilizing the handle 2806 of the stabilizer inserter instrument 2800 to steer and advance down the retracted surgical corridor, the base nose 2311 at the leading end of the stabilizer is inserted into a keel track channel 2255, 2265 and advanced in a first direction in a linear path by the surgeon, tapping at the trailing end of the stabilizer inserter instrument 2800 into the vertebrae until the stabilizer 2300 reaches the stabilizer stop 2276 and achieves an operative relationship with the spacer 2200. As the stabilizer is advanced, the leading edge 2340 cuts through the bone portion between the drilled bore/channel and the adjacent surface on the bone portion. Alternatively, a complementary slot for receiving the web 2320 can be pre-formed in the bone portion, making the sharp leading edge 2340 potentially unnecessary. Even if this slot is pre-formed, the sharp leading edge 2340 may still perform a valuable function in aligning/guiding the web 2320 at the slot. The self-retaining tabs/barbs 2350 will prevent backout of the stabilizer 2300 from the spacer channels 2255, 2265. The stabilizer inserter 2800 is then unthreaded from the stabilizer 2300 and removed.

[0232] A threaded spreader 2421, as shown in FIG. 24B, is then attached to the spreader driver 2430 in a first position and advanced by being turned around its lengthwise axis into the stabilizer 2300 central bore 2331 into a second position, wherein the spreader is fully seated. FIG. 25B illustrates a spacer/cage 2200 with a stabilizer 2300 inserted therein. The spreader 2421 is partially seated within the stabilizer 2300 wherein the nose 2422 of the spreader 2421 begins contact with the internal surface of the stabilizer tabs 2366, as shown in FIG. 25B. FIG. 25A is a similar illustration, but the spreader 2421 has yet to contact tabs 2366. A portion of the stabilizer is resected for viewing purposes.

[0233] The reconfigurable stabilizer 2300 is fully secured when the spreader 2421 is fully seated, and changed from this first state by causing tabs 2366 to be deflected from a first relaxed position into a second position and forcibly into the surrounding bone, representing a locked state for the stabilizer. The bone-engaging tabs 2366 produce a localized compression that reconfigures the adjacent bone so as to further enhance compression between that bone portion and the spacer. The spacer stabilizer assembly 2400, situated within the partially resected vertebrae and with stabilizer tabs 2366 fully deployed, is illustrated in FIG. 24A. The spreader driver 2430 may now be removed. Following the steps above, bores for other stabilizers can be drilled and other stabilizers can be inserted and locked into position in like manner to engage both bone portions 2412, 2413. The spacer inserter tool 2600 is then removed. The wound closure procedure may then be initiated. The instrumentation preferably functions by movement along an axis/line coincident with the implant insertion axis, thereby minimizing the incision size.

[0234] The joined spacer/cage 2200 and stabilizer 2300 implant may be removed by unscrewing and therein unlocking the spreader(s) 2421 and removing it. The spacer/cage 2200 and stabilizer 2300 implant can then be removed by reattaching the inserter tool 2600 and pulling opposite to the path/line of insertion. If necessary, the stabilizer 2300 may be backed out from the channels/tracks 2255, 2265 by shearing the spacer track material, thereby releasing the tabs/barbs 2350.

[0235] Insertion and removal of the spacer and stabilizer is affected by movement of those components in a single plane, and in a preferred form in parallel lines, whereby the overall procedure is minimally invasive.

[0236] One or more surgical kits may be provided containing all implants and instruments required to perform the surgery. These kits may include implants such as various sized spacers, stabilizers, and spreaders. They may also include instruments that directly interface with these implants such as spreader drivers, spacer inserter tools, stabilizer inserters and drill guides. In addition, the kits may contain scalpels, drills, guide wires, dilators, retractors, lighting sources, and instruments for disc preparation such as shavers, curettes, and rongeurs. A kit containing a nerve monitoring system may also be provided.

[0237] In the preferred embodiment, the distance from the central axis of the drilled hole in the vertebral bodies to the nearest spacer opposing surface is on the order of 0.5 mm greater than the distance between the central axis of the stabilizer cylindrical wall and the nearest spacer opposing surface that produces a captive force. In other words, the first surface 2380 of the base wall 2310 is spaced from the axis A of the wall 2330 a distance that is less than the distance between the surface 2266 bounding the channel 2255 and the

central axis of the drilled bore/channel in the bone portion. This discrepancy in distance causes there to be approximately 0.5 mm movement that preferably causes compression of parts of the spacer and bone portion between the cylindrical wall surface 2303 and the opposing surface 2380 that is progressively developed as the spacer and stabilizer are moved from their pre-assembly relationship into their operative relationship. This compression force resulting from the cooperative interaction of the stabilizer, bone portion, and spacer, as the spacer and stabilizer are placed into operative relationship with each other and the bone portion, assures that the vertebral body/bone portion is held tightly against the adjacent interbody/spacer surface, therein, apart from imparting stability, improving the opportunity for a successful fusion. Also, by keeping the cylindrical wall relatively close to the endplate (approximately 5 mm above the endplate), by applying a bearing force over a majority of the end plate extent where the stabilizer overlies the same, the cylindrical wall is securely kept in the hard endplate bone. If the cylindrical wall is too deep into the vertebrae (web wall is too tall), the cylindrical wall will reside in the softer bone of the vertebral body and therein is more likely to deform the softer bone, potentially allowing the implant to loosen.

[0238] Biomechanical testing of the spacer stabilizer assembly 2400 revealed static torsion of 36 Newton Meters with 9 degrees rotation. This is roughly triple the results of a pedicle screw corpectomy model. Other performance measures of this assembly include static yield compression of 4190 Newtons, and an ultimate compression strength of 4798 Newtons. Stability was demonstrated in all planes of movement. This positive fixation results instantaneously and is only further enhanced by eventual bone ingrowth.

[0239] The bodies 2290 of the spacers in these embodiments are preferably manufactured using biocompatible polymer such as PEEK (polyetheretherketone) or similar materials, but could be made using metals such as titanium or titanium alloys such as Ti64, or stainless steel alloys, or other biocompatible materials. The stabilizer is preferably manufactured using these metals although strong polymers or composites are also usable. Materials discussed and disclosed earlier may also be used. The implant may utilize coatings such as hydroxyapatite or other surface treatments to assist surface bone adhesion to the implant.

[0240] The spacer is shown with a symmetrical configuration for insertion selectively in either of opposite directions between vertebrae and in an inverted orientation.

DISCUSSION OF ALTERNATIVES

[0241] The device disclosed may be used in a variety of locations in the body—wherever there is a need to secure an implant to bone or bone fragments. For example, the device may be configured to secure the stemmed tibial plate in a total knee replacement surgery. The device is also well suited for stabilizing the sacral iliac joint. Other possible bone portion fusions include: ankle and subtalar fusions; MTP joint fusions of the great toe; opening wedge high tibial and distal tibial osteotomies; and metacarpal hand fusions. Spinal applications include cervical, thoracic and lumbar.

[0242] In the preferred embodiment, the stabilizer deflection gap is situated in a plane generally perpendicular to the web wall, thereby minimizing forces which may cause the vertebral body to crack. Alternatively other portions of the stabilizer cylindrical wall could be configured to expand and

retain position. For example, the leading portion of the cylindrical wall could be longitudinally gapped to expand in diameter.

[0243] The device may be used at adjacent vertebral levels. In the preferred embodiment the cylindrical wall portion is kept near the endplate thereby leaving an adequate amount of the vertebral body bone between the adjacent level implants. Alternatively, the channels/keel tracks 2255/2265 could be staggered on the implant, thereby increasing distance between each stabilizer and thereby maximizing bone mass therebetween.

[0244] As an alternative, the reconfigurable body portion of the stabilizer can be deployed by a camming action rather than the spreader utilized in the preferred embodiment. A cam situated at the end of the spreader would deploy and lock the reconfigurable body tabs upon rotation of the camming spreader.

[0245] As another alternative, the upper and lower stabilizers may slidably engage or otherwise interlock with each other, thereby relieving some of the forces endured by the channels or keel/tracks of the implant. Similarly, the upper and lower stabilizers may have a continuous web wall joining them. For example, this web may have a side lying flat track or base wall on the web to interconnect into a stabilizer attachment such as a keel track on the side of the implant body.

[0246] As another alternative, the implant body may be configured with more than one stabilizer attachment site to accommodate a plurality of stabilizers on one side. For example, the implant body portion could be modified for keel tracks on both sides of the graft portion. This configuration may be advantageous in an interbody device for anterior surgical approach.

[0247] As another alternative, the web wall is manufactured integral with the spacer and slides in with the implant wherein the cylindrical wall portion slides over the web into pre-drilled holes afterward.

[0248] Each of the described embodiments might be further modified by additionally using screws, adhesives, or other supplementary fixation structure.

[0249] Throughout, where there are cooperating components on separate elements, it is contemplated that the described placement of these components could be reversed. For example, the tabs/barbs 2350, shown on the stabilizers 2300, could be placed on the spacer/cage 2200 with the complementary undercut regions 2225 provided on the stabilizer 2300. Different combinations and numbers of these paired components can also be utilized.

[0250] Other mechanisms may be utilized to block the stabilizer in its operative relationship with the spacer. For example, detent arrangements, such as that utilizing a ball element, might be substituted for, or used in conjunction with, the described structure.

[0251] While the spacer is described above to be placed between adjacent bone portions before the stabilizer is moved from a pre-assembly relationship therewith into an operative relationship, the stabilizer could be put in place first followed by placement of the spacer. This is made possible through the use of a jig.

[0252] While assembly paths of all components are described as linear, this is also not a requirement. Further, the assembly paths for multiple stabilizers, while shown to be parallel, need not be so oriented.

[0253] It is also contemplated that structures features from all different embodiments are combinable in different combinations.

[0254] The foregoing disclosure of specific embodiments is intended to be illustrative of the broad concepts comprehended by the invention.

1. A method for stabilizing first and second adjacent bone portions, the method comprising the steps of:

providing a spacer;

providing a stabilizer,

the spacer and stabilizer configured to be movably guidingly, one relative to the other, between a pre-assembly relationship and an operative relationship; and

placing the spacer and stabilizer into an operative relationship with the first and second adjacent bone portions by:

a) placing the spacer between the first and second adjacent bone portions; b) directing the stabilizer into the first bone portion; and c) changing the spacer and stabilizer from their pre-assembly relationship into their operative relationship,

whereby as an incident of the spacer and stabilizer being changed from their pre-assembly relationship into the operative relationship with each other and the first and second bone portions, the spacer, stabilizer and first bone portion cooperate to cause the first bone portion and spacer to be urged towards each other.

2. The method for stabilizing first and second adjacent bone portions according to claim 1 wherein the step of providing a stabilizer comprises providing a stabilizer with a body comprising first and second spaced walls joined by a web, the first and second spaced walls respectively having first and second surfaces that face each other.

3. The method for stabilizing first and second adjacent bone portions according to claim 2 further comprising the step of pre-forming a first channel in the first bone portion and the step of directing the stabilizer into the first bone portion comprises moving the second wall guidingly in the first channel between a first position and a second position, the second wall in the second position with the spacer and stabilizer in the operative relationship with the first and second adjacent bone portions.

4. The method for stabilizing first and second adjacent bone portions according to claim 3 wherein the spacer has a first surface that faces a first surface on the first bone portion with the spacer between the first and second bone portions, the stabilizer web has a sharp leading edge and the step of directing the stabilizer into the first bone portion comprises the step of causing the sharp leading edge on the web to cut through the first bone portion between the first channel and first surface on the first bone portion.

5. The method for stabilizing first and second adjacent bone portions according to claim 3 wherein the step of providing a stabilizer comprises providing a stabilizer having a length, with the second wall having a lengthwise axis, wherein the second surface has a convex curvature, as seen in cross-section taken transversely to the length of the stabilizer, with a radius at or adjacent to the lengthwise axis of the second wall, the stabilizer further having a leading end and a nose with a tapered surface portion that is angled between the leading end and the second surface, wherein the spacer is placed between the first and second bone portions before the stabilizer is directed into the first bone portion and as an incident of the stabilizer being changed from its first position

into its second position, the tapered nose surface bears against the first bone portion and progressively wedges the first bone portion towards the spacer.

6. The method for stabilizing first and second adjacent bone portions according to claim 5 wherein the first and second bone portions are adjacent first and second vertebrae, the spacer has oppositely facing first and second surfaces and the first vertebra has a first endplate with a first surface facing the first surface on the spacer, the first endplate has a first dimension parallel to the length of the stabilizer with the spacer and stabilizer in their operative relationship, and the step of providing a stabilizer comprises providing a stabilizer wherein the second surface on the stabilizer applies a force on the first bone portion over a majority of the first dimension of the first surface of the first endplate that urges the first endplate surface against the first spacer surface.

7. The method for stabilizing first and second adjacent bone portions according to claim 5 wherein the step of placing the spacer and stabilizer into operative relationship with the first and second adjacent bone portions comprises causing a part of the first bone portion and a part of the spacer to be compressively maintained between the first and second stabilizer surfaces.

8. The method for stabilizing first and second adjacent bone portions according to claim 5 wherein the step of directing the stabilizer into the first bone portion comprises advancing the stabilizer guidingly in a path in a first direction and further comprising the step of reconfiguring the stabilizer, with the spacer and stabilizer in the operative relationship with the first and second adjacent bone portions, into a locked state to block movement of the stabilizer relative to the first bone portion oppositely to the first direction.

9. The method for stabilizing first and second adjacent bone portions according to claim 8 wherein the stabilizer comprises a first tab and the step of reconfiguring the stabilizer from the first state into the locked state comprises moving the first tab from a first position into a second position wherein the first tab bears against the first bone portion.

10. The method for stabilizing first and second adjacent bone portions according to claim 9 wherein the step of providing a stabilizer comprises providing a stabilizer with a movable spreader and the step of reconfiguring the stabilizer comprises moving the spreader from a first position into a second position as an incident of which the first tab is moved from its first position into its second position.

11. The method for stabilizing first and second adjacent bone portions according to claim 10 wherein the step of providing a stabilizer comprises providing a stabilizer that is turned about an axis relative to the second wall to change the spreader between its first and second positions.

12. The method for stabilizing first and second adjacent bone portions according to claim 9 wherein the first tab has a hinge portion and the step of moving the tab comprises moving the tab about the hinge portion from its first position into its second position.

13. The method for stabilizing first and second adjacent bone portions according to claim 9 wherein the first tab has a live hinge and the step of moving the first tab comprises moving the tab about the live hinge portion from its first position into its second position.

14. The method for stabilizing first and second adjacent bone portions according to claim 8 wherein the step of providing a stabilizer comprises providing a stabilizer with first and second movable tabs and the step of reconfiguring the

stabilizer from the first state into the locked state comprises moving the first tab from a first position into a second position wherein the first tab bears against the first bone portion, wherein the second tab defines the tapered nose surface portion.

15. The method for stabilizing first and second adjacent bone portions according to claim 14 wherein the step of providing a stabilizer comprises providing a stabilizer with a movable spreader and the step of reconfiguring the stabilizer comprises moving the spreader from a first position into a second position as an incident of which the first tab is moved from its first position into its second position and the second tab is moved from a first position into a second position.

16. The method for stabilizing first and second adjacent bone portions according to claim 15 wherein the step of moving the spreader comprises moving the spreader from its first position into its second position and against each of the first and second tabs to change each of the first and second tabs from its first position into its second position.

17. The method for stabilizing first and second adjacent bone portions according to claim 2 wherein the step of providing a spacer comprises providing a spacer with a channel and the step of changing the spacer and stabilizer from their pre-assembly relationship into their operative relationship comprises moving a part of the stabilizer guidingly within the channel.

18. The method for stabilizing first and second adjacent bone portions according to claim 17 wherein the steps of providing a spacer and stabilizer comprise providing a spacer and stabilizer each with a blocking surface, which blocking surfaces abut to block the spacer and stabilizer from moving out of their operative relationship.

19. The method for stabilizing first and second adjacent bone portions according to claim 17 wherein the steps of providing a spacer and stabilizer comprise providing a spacer and stabilizer each with a blocking surface which blocking surfaces are brought into confronting relationship as an incident of the spacer and stabilizer being changed from their pre-assembly relationship into their operative relationship.

20. The method for stabilizing first and second adjacent bone portions according to claim 18 further comprising the step of reconfiguring one of the spacer and stabilizer with the spacer and stabilizer in their operative relationship to thereby place the blocking surfaces on each of the spacer and stabilizer in confronting relationship.

21. The method for stabilizing first and second adjacent bone portions according to claim 19 wherein the steps of providing a spacer and stabilizer comprise providing a deflectable tab defining the blocking surface on one of the spacer and stabilizer that deflects in one direction as the spacer and stabilizer are changed from their pre-assembly relationship into their operative relationship and is moved oppositely to the one direction under a restoring force to place the blocking surface on the one of the spacer and stabilizer into confronting relationship with the blocking surface on the other of the spacer and stabilizer as an incident of the spacer and stabilizer realizing the operative relationship.

22. The method for stabilizing first and second adjacent bone portions according to claim 20 wherein the step of providing a stabilizer comprises providing a stabilizer wherein the deflectable tab is provided on the first wall of the stabilizer.

23. The method for stabilizing first and second adjacent bone portions according to claim 20 wherein the step of

providing a stabilizer comprises providing a stabilizer wherein the first wall and web on the stabilizer cooperatively define a “T”-shaped portion.

24. The method for stabilizing first and second adjacent bone portions according to claim **23** wherein the step of providing a spacer comprises providing a spacer with a “T”-shaped channel that is complementary to the “T”-shaped portion of the stabilizer and the step of changing the spacer and stabilizer from their pre-assembly relationship into their operative relationship comprises moving the “T”-shaped portion of the stabilizer guidingly within the “T”-shaped channel.

25. The method for stabilizing first and second adjacent bone portions according to claim **24** wherein the step of providing a stabilizer comprises providing a stabilizer with the second surface on the second wall having a convexly curved shape.

26. The method for stabilizing first and second adjacent bone portions according to claim **25** wherein the step of providing a stabilizer comprises providing a stabilizer with the second wall on the stabilizer having a cylindrical shape.

27. The method for stabilizing first and second adjacent bone portions according to claim **2** wherein the step of providing a stabilizer comprises providing a stabilizer wherein the first wall and web are substantially flat and cooperatively define a “T”-shaped portion and the second surface on the second wall has a convexly curved shape.

28. The method for stabilizing first and second adjacent bone portions according to claim **1** further comprising the step of reconfiguring the stabilizer from a first state, with the spacer and stabilizer in the operative relationship with the first and second adjacent bone portions, into a locked state by moving a part of the stabilizer forcibly against the first bone portion.

29. The method for stabilizing first and second adjacent bone portions according to claim **1** wherein the stabilizer is directed into the bone portion before the spacer and stabilizer are changed from their pre-assembly relationship into their operative relationship.

30. The method for stabilizing first and second adjacent bone portions according to claim **1** further comprising the step of providing a second stabilizer and connecting the second stabilizer to each of the spacer and the second bone portion.

31. The method for stabilizing first and second adjacent bone portions according to claim **8** further comprising the step of reconfiguring the stabilizer after it has been changed into the locked state back into the first state and thereafter separating the stabilizer and spacer from the first and second bone portions.

32. The method for stabilizing first and second adjacent bone portions according to claim **3** further comprising the steps of providing a guide structure on the spacer and using the guide structure to pre-form the first channel in the first bone portion.

33. The method for stabilizing first and second adjacent bone portions according to claim **28** wherein the step of moving the part of the stabilizer forcibly against the first bone portion comprises the step of moving the part of the stabilizer forcibly against the first bone portion in a manner so as to thereby urge the first bone portion and spacer against each other.

34. The method for stabilizing first and second adjacent bone portions according to claim **1** wherein the step of pro-

viding a spacer comprises providing a spacer with first and second spaced bores and further comprising the step of providing an auxiliary tool that is used in conjunction with the spacer by connecting the auxiliary tool using at least one of the first and second bores.

35. The method for stabilizing first and second adjacent bone portions according to claim **34** further comprising the step of connecting the auxiliary tool to the spacer by placing first and second connectors on the auxiliary tool one each into the first and second bores.

36. The method for stabilizing first and second adjacent bone portions according to claim **34** further comprising the step of connecting the auxiliary tool to the spacer by using either one, but only one, of the first and second bores.

37. The method for stabilizing first and second adjacent bone portions according to claim **19** wherein the steps of providing a spacer and stabilizer comprise providing first and second deflectable tabs each defining a blocking surface on at least one of the spacer and stabilizer that each deflects in a direction as the spacer and stabilizer are changed from the pre-assembly relationship into the operative relationship and are moved oppositely to their deflecting direction under restoring forces to place each of the blocking surfaces separately into confronting relationship with a blocking surface on the spacer or stabilizer as an incident of the spacer and stabilizer realizing the operative relationship.

38. The method for stabilizing first and second adjacent bone portions according to claim **1** wherein the step of placing the spacer and stabilizer into an operative relationship with the first and second adjacent bone portions comprises moving the spacer and stabilizer substantially only in a single plane and parallel to a single line.

39. In combination:

a spacer that can be placed between first and second adjacent bone portions,

the spacer having oppositely facing surfaces; and

a stabilizer that is movable guidingly relative to the spacer in a first path in a first direction: a) from a position wherein the stabilizer is in a pre-assembly relationship with the spacer; and b) into a position wherein the stabilizer is in an operative relationship with the spacer, the stabilizer capable of being directed in the first direction while being moved in the first path relative to the spacer into one of the first and second bone portions so as to urge a surface of the one bone portion forcibly against one of the spacer surfaces with the spacer and stabilizer in operative relationship with each other and the first and second adjacent bone portions,

the stabilizer comprising a body comprising first and second spaced walls joined by a web,

the first and second spaced walls respectively having first and second surfaces that face each other,

the second wall having a leading end and a surface portion that is angled with respect to the first path to produce a wedging action against the one bone portion as the stabilizer is advanced in the first direction in the first path into the one bone portion,

the wedging action causing a part of the one bone portion and a part of the spacer to be urged towards each other as the spacer and stabilizer are moved into operative relationship with each other and the first and second adjacent bone portions.

40. The combination according to claim **39** wherein the stabilizer has a length and a lengthwise axis, the first path is

substantially straight along a first line and the second surface has a convex curvature as seen in cross-section taken transverse to the length of the stabilizer with a radius that is centered on a line parallel to the lengthwise axis of the stabilizer.

41. The combination according to claim 40 wherein the stabilizer has a nose defining the tapered surface portion that is angled with respect to the central axis of the stabilizer.

42. The combination according to claim 41 wherein the second wall has a cylindrical shape and the nose defines the surface portion that tapers between a leading end of the second wall and the second surface.

43. The combination according to claim 42 wherein the nose is split to define separate tabs and one of the tabs is selectively movable wherein the one tab forcibly engages the one bone portion to change the stabilizer from a first state into a locked state to prevent movement of the stabilizer relative to the one bone portion with the spacer and stabilizer in operative relationship with each other and the first and second adjacent bone portions.

44. The combination according to claim 43 further in combination with a spreader that is selectively movable relative to the stabilizer to thereby change the stabilizer from the first state into the locked state.

45. The combination according to claim 39 wherein the first wall and web are substantially flat and cooperatively define a "T"-shaped portion and the spacer has a "T"-shaped channel that cooperates with the "T"-shaped portion of the stabilizer to guide relative movement between the pre-assembly and operative relationships.

46. The combination according to claim 45 wherein the second wall has a substantially cylindrical shape that defines the second surface.

47. The combination according to claim 46 wherein the first surface resides in a first plane and the cylindrical shape has a central axis and the first plane and central axis of the cylindrical shape are substantially parallel.

48. The combination according to claim 46 wherein the first surface resides in a first plane and the cylindrical shape

has a central axis and the first plane and central axis of the cylindrical shape are at an angle with respect to each other.

49. The combination according to claim 39 wherein the spacer defines a channel to guide the stabilizer as the spacer and stabilizer are relatively moved between their pre-assembly and operative relationships and the spacer has a stop portion that abuts the stabilizer moving in the first direction so that the spacer and stabilizer can be consistently placed in their operative relationship.

50. The combination according to claim 49 wherein the spacer and stabilizer have cooperating blocking surfaces that abut to block the spacer and stabilizer from moving out of their operative relationship.

51. The combination according to claim 50 wherein the blocking surfaces contact each other as an incident of the spacer and stabilizer realizing the assembly relationship.

52. The combination according to claim 51 wherein one of the blocking surfaces is on a movable tab on one of the spacer and stabilizer, the movable tab deflected in one direction as the spacer and stabilizer are moved from their pre-assembly relationship toward their operative relationship and moving under a restoring force oppositely to the one direction upon the operative relationship between the spacer and stabilizer being realized.

53. The combination according to claim 39 wherein the second wall has a cylindrical shape with a central axis and further in combination with a drill guide on the spacer and a drill that is movable controllably along the drill guide parallel to a central axis of the drill, the spacer having a third surface to which the first surface of the stabilizer abuts with the spacer and stabilizer in their operative relationship and a first distance between the central axis of the drill on the drill guide and the third surface is greater than a second distance between the central axis of the second wall and the first surface.

54. The combination according to claim 53 wherein the first distance is greater than the second distance by on the order of 0.5 mm.

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